Implementing the new Machinery Directive 2006/42/EC in the United Kingdom

A Consultation Document

September 2007

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Introduction

This consultation seeks the views of businesses, manufacturers, retailers, producers and enforcement authorities on a set of draft Regulations to transpose Commission Directive 2006/42/EC\(^1\) (the revised Machinery Directive henceforth referred to as ‘2006/42/EC’) into UK law. 2006/42/EC will regulate the placing on the market, and the putting into service, of machinery across the United Kingdom and the European Union, as currently undertaken by Commission Directive 98/37/EC\(^2\) which it replaces. The new Directive aims to provide greater clarity than the old directive, e.g. with a new definition of the core concept of ‘machinery’ and in the dividing lines between itself and the Lifts and Low Voltage Directives. Another significant change is the introduction of a quality assurance conformity assessment module as an option for relevant manufacturers. Some of the other changes are described below but, in general, the new directive follows the same principles as the old one - the changes are largely a question of tidying up acknowledged flaws in the old directive and addressing some of the difficulties that have been experienced in making it work properly in practice. Both the old and the new directives adhere to the principles of the ‘New Approach’ which is a regulatory model used by the EU across several product sectors for dismantling non-tariff barriers to trade (through the harmonisation of national essential safety requirements). The European Commission’s ‘Blue Guide’ explains the principles and the concepts behind the New Approach.

Important Note:

Please note that this consultation does not seek views on the provisions of the Directive itself but on our proposals to implement it.

Consultation begins on: 25 / 09 / 2007
Consultation ends on: 18 / 12 / 2007

Please see Section 3 for details of whom to respond to.

\(^1\) Text of Directive 2006/42/EC at Annex A
\(^2\) Repealed from 29 December 2009
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1. **Context**

1.1 In 2001 the Commission brought forward proposals to amend Directive 98/37/EC on the approximation of the laws of Member States relating to machinery. After negotiations between the institutions of the EU culminating in final agreement of a text late in 2005 the new Directive was published in the Official Journal of the European Union on 9 June 2006\(^3\). It repeals Directive 98/37/EC.

1.2 Subject to some very minor exceptions Article 26 of the new Machinery Directive (MD) requires all Member States to have transposed the Directive into their domestic legislation by 29 June 2008, and to apply the Directive’s provisions from 29 December 2009. Up until 28 December 2009 only the existing directive 98/37/EC has legal application. From 29 December 2009 only the new directive, 2006/42/EC, has legal application. In other words there will be not be a ‘transitional period’ where manufacturers have a choice of which directive to apply and so the existing Directive, and thus the existing implementing Regulations, remain applicable to machinery first placed on the market or put into service prior to 29 December 2009.

2. **Draft Machinery Regulations - Key changes**

2.1 The new draft Machinery Regulations will implement Directive 2006/42/EC which also amends 95/16/EC, the EU Lifts Directive. In summary these Regulations:

- apply to all machinery, as defined in the directive and not otherwise excluded, that is placed on the EU market, or put into use within the EU, for the first time, including machinery used but not readily available commercially, eg company prototypes, unless such equipment is specifically exempted

- provide a new definition of the core term “machinery”, itself based on the revised definition of this term which is introduced by 2006/42/EC, but with some slight modifications and an altered format in an attempt to aid understanding

- introduce new definitions that 2006/42/EC provides of some other key concepts, specific to the machinery directive, into UK legislation, such as ‘safety components’ and ‘lifting accessories’ but, in the case of the former, with an indicative list to back up the basic 2006/42/EC definition, and in the case of the latter formatted slightly differently from how it appears in 2006/42/EC, again for the reasons described above

- incorporate into UK legislation the new concept, introduced by 2006/42/EC, of ‘partly completed machinery’, similarly with some small adjustments to the actual wording used in 2006/42/EC to try to make it easier to understand in a UK setting. The new concept tries to address some current uncertainties about the respective duties of operators at various stages along complex production chains

- introduce, with some adjustments, the definitions which 2006/42/EC now explicitly provides of some important concepts that apply generally to ‘New Approach’ directives such as ‘manufacturer’ and ‘placing on the market’ which the previous Machinery Directive used but did not explicitly define thus leaving interpretation to be taken from other sources such as UK domestic legislation or ‘the ‘Blue Guide’

\(^3\) OJEU L 157 09.06.2006 page 0024 et seq
• bring builders’ goods hoists and cartridge operated tools into the scope of the Regulations

• provide greater clarity on the interface with the UK Lifts Regulations by amending those regulations as required by Article 24 of 2006/42/EC

• include a new voluntary full quality assurance module that will allow certain manufacturers - or ‘responsible persons’ in the terminology of the regulations - of Annex IV products to carry out conformity assessment more efficiently than has been possible previously and should be a particular benefit to those manufacturing prototype and bespoke machinery

• introduce the new, lighter procedure for manufacturers using harmonised standards to produce hazardous products (as listed in Annex IV) whereby they are no longer required to deposit technical documentation for safe keeping by a notified body

• make some small changes to the contents of Declarations of Conformity which will equip the enforcement authorities (sometimes referred to as the market surveillance authorities) with better means of tracing products. This will, in turn, make it easier for them to monitor the market and take action against non-compliant machinery and those supplying it and thus to ensure fair competition across the sector

• reproduce, in the form in which they appear in 2006/42/EC, the new set of essential safety requirements which are in a clearer format and a more logical sequence than in the existing regulations. The new set of requirements are generally considered to advance the ‘state of the art’ so, notwithstanding the absence of a transitional period noted above in paragraph 1.2, manufacturers who take on board the new requirements ahead of their officially coming into force in late 2009, will find that they automatically fulfil the old set of requirements. The ‘Question and Answer’ texts, no’s 1 and 2, in Annex C provide further confirmation of this point.

2.2 With the sole exception of the Office of Rail Regulation becoming an additional enforcement authority (because of some recent changes in the Health and Safety Executive’s range of responsibilities) the Regulations do not make any changes to areas in the existing regulations which are not affected by the coming into force of 2006/42/EC such as:

• the procedures for enforcing the requirements of the directive

• the penalties for non-compliance.

3. How to respond

3.1 Responses should be sent to:

Mike Dodds
Department of Business, Enterprise & Regulatory Reform (BERR)
Sustainable Development & Regulation Directorate
Bay 384
1 Victoria Street
London SW1H 0ET
3.2 When responding please state whether you are responding as an individual or representing the views of an organisation. If responding on behalf of an organisation, please make it clear who the organisation represents and, where applicable, how the views of members were assembled.

3.3 An electronic version of the whole consultation document is available in pdf format on the BERR central consultation webpage, see http://www.berr.gov.uk/consultations and also on the Sustainable Development & Regulation Directorate website at http://www.berr.gov.uk/innovation/strd/ecdirect/page12543.html

The Consultation Response form, as a stand alone Microsoft Word format document, can also be downloaded from both pages.

3.4 A list of those organisations and individuals initially being consulted is at Annex F. We would welcome suggestions of others who you think may wish to be involved in this consultation exercise.

4. Additional copies

4.1 You may make copies of this document without seeking our permission. Alternatively, further printed copies of the consultation document can be obtained from:

BERR Publications Orderline
ADMAIL 528
London SW1W 8YT.

Tel: 0845 015 0010
Fax: 0845 015 0020
Minicom: 0845 015 0030

4.2 This document can be obtained in alternative forms on application to the contact named above.

5. Confidentiality & Data Protection

5.1 Information provided in response to this consultation, including personal information, may be subject to publication or disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004. If you want other information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence.

5.2 In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.
5.3 The Department will process your personal data in accordance with the DPA and in the majority of circumstances this will mean that your personal data will not be disclosed to third parties.

6. Help with queries

6.1 Questions about the policy issues raised in the document can be addressed to:

Mike Dodds at the 1 Victoria Street address.

7. Arrangement of the proposals and other issues of interpretation and impact


7.2 The draft Regulations cover all aspects of the placing on the market and the putting into service of machinery unless such machinery is explicitly exempted from the directive.

7.3 It is recognised that the new Directive will raise some issues of interpretation which will, of course, be relevant to how the new Regulations are interpreted in the UK. The European Commission will prepare a body of guidance on the directive, in consultation with the EU Member States and industry stakeholders, over the next few years. This process has already begun and the guidance that has emerged so far is reproduced at Annex C. The guidance will be internet-based to facilitate quicker, easier and regular updating.

7.4 Because these proposals have cost implications for businesses and other bodies it is necessary to include with this consultation an Impact Assessment (IA). At the time of this consultation the IA will be partial. Finalisation will be effected following an analysis of the consultation responses.

7.6 The draft Regulations are arranged into 7 parts in total with supporting Schedules (an overview is given immediately below, more detail can be found in the transposition note at Annex E). The draft Regulations in full can be found at Annex B. Some elements of the draft 2008 Regulations are essentially unchanged from the existing Supply of Machinery (Safety) Regulations 1992 and subsequent Statutory Instruments in 1994 and 1995. It would be helpful if you were to focus your comments, in the main, on those new or revised elements identified in the ‘Key Changes’ section above. If there are other changes you are aware of that are not identified there and you wish to find out how they have been addressed in the draft regulations the transposition note (see Annex E) should assist you.

\(^4\) 2006/42/EC is designated as a text with EEA relevance. It is expected that it will be adopted by the EEA Joint Committee (as the previous Machinery Directives have been) so that it will apply throughout the European Economic Area by the time it comes into force. The draft Regulations have been drafted on this assumption: if 2006/42 is not adopted by the EEA Joint Committee before 29 June 2008, some minor changes will have to be made to them to reflect this

\(^5\) This directive consolidated Machinery Directives 89/392/EC, 91/368/EEC, 93/44/EEC and 93/68/EEC
7.7 The Regulations

Part I: Preliminary

Regulations 1 - 3 transpose Article 26 and parts of Articles 2 and 4.

Part 2: Application

Regulations 4 - 6 transpose Article 1 and parts of Article 2.

Part 3: General prohibitions and obligations

Regulations 7 - 9 transpose Article 13 and parts of Articles 5, 7, 12, 16.

Part 3 (continued): Conformity assessment procedures

Regulations 10 - 12 transpose part of Article 12.

Part 4: CE Marking

Regulations 13 - 15 transpose parts of Articles 5, 7 and 16.

Part 5: Notified bodies

Regulations 16 - 19 transpose Article 14.

Part 6: Enforcement

Regulations 20 - 23 transpose Article 17.

Part 7: Miscellaneous

Regulations 24 - 25 transpose Article 24.

Regulations 26 - 27 transpose Article 26\(^6\).

Schedules

Schedule 1: Regulations revoked.


Schedule 3: Products to which the Regulations do not apply.

Schedule 4: Appeals against Notified Body determinations under Regulation 18 (4).

Schedule 5: Enforcement.

\(^6\) These disapply certain provisions of domestic health and safety legislation which would otherwise duplicate the effect of our Machinery Regulations: the scope of the disapplications may change in the final version of the Regulations pending the outcome of ongoing revisions of some of the domestic provisions concerned.

Schedule 7: Consequential Amendments.

Schedule 8: Consequential Disapplications.

7.8 Because Article 6 of the draft framework directive on the use of pesticides relates to the placing on the market of spraying equipment it overlaps, in its supply, with the 2006/42/EC. Originally the intention was to have had a separate directive wholly related to pesticide issues. The Commission's Legal Service has, however, advised against directives having a double legal basis. The Commission have therefore reviewed this outline proposal and now propose to add the design and supply of such pesticide equipment to the new Machinery Directive but not its user applications, ie examination and maintenance of such equipment. There will also be additional essential health and safety requirements added to annex 1 of the new directive on protecting the environment. The Commission’s present intention is that these changes should be dovetailed with the timetable contained in Article 26 of 2006/42/EC.

8. **What happens next?**

8.1 The results of this consultation exercise, including a summary of the views expressed, will be published approximately three months after the close of the exercise on the BERR website, see [www.berr.gov.uk/innovation/strd/ecdirect/page12543.html](http://www.berr.gov.uk/innovation/strd/ecdirect/page12543.html)

8.2 The summary will also be available in hard copy form on request.

8.3 Please remember it is not the Directive on which we would like your comments - the text has been approved by the European Parliament and The Council and cannot be changed. It is on our proposals to implement the Directive that we seek your views.

8.4 Subject to Ministerial approval it is anticipated that the new Regulations will be made and laid before Parliament using the Negative Resolution procedure by May 2008.

8.5 Once made the Regulations will be published and may then be viewed on the OPSI (Office of Public Sector Information) web site at [http://www.opsi.gov.uk/stat.htm](http://www.opsi.gov.uk/stat.htm)

9. **Conduct of the consultation**

9.1 If you have any comments, concerns or reservations about the way in which this consultation has been conducted these should be sent to:

Kathleen McKinlay  
Consultation Co-coordinator  
Department of Business, Enterprise & Regulatory Reform (BERR)  
Bay 566  
1 Victoria Street  
London  
SW1H OET  
E-mail mailto:kathleen.mckinlay@berr.gsi.gov.uk  
Tel: 020 7215 2811

9.2 A copy of the Code of Practice on Consultation is included at the end of Annex G.
THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Economic and Social Committee (2),

Acting in accordance with the procedure laid down in Article 251 of the Treaty (3),

Whereas:


(2) The machinery sector is an important part of the engineering industry and is one of the industrial mainstays of the Community economy. The social cost of the large number of accidents caused directly by the use of machinery can be reduced by inherently safe design and construction of machinery and by proper installation and maintenance.

(3) Member States are responsible for ensuring the health and safety on their territory of persons, in particular of workers and consumers and, where appropriate, of domestic animals and goods, notably in relation to the risks arising out of the use of machinery.

(4) In order to ensure legal certainty for users, the scope of this Directive and the concepts relating to its application should be defined as precisely as possible.

(5) The Member States’ mandatory provisions governing construction site hoists intended for lifting persons or persons and goods, which are often supplemented by de facto compulsory technical specifications and/or by voluntary standards, do not necessarily lead to different levels of health and safety but, because of their disparities, do nevertheless constitute barriers to trade within the Community. Moreover, the national systems for the conformity assessment and certification of these machines diverge considerably. It is therefore desirable not to exclude from the scope of this Directive construction site hoists intended for lifting persons or persons and goods.

(6) It is appropriate to exclude from the scope of this Directive, weapons, including firearms, that are subject to Council Directive 91/477/EEC of 18 June 1991 on control of the acquisition and possession of weapons (6): the exclusion of firearms should not apply to portable cartridge-operated fixing and other impact machinery designed for industrial or technical purposes only. It is necessary to provide for transitional arrangements enabling Member States to authorise the placing on the market and putting into service of such machinery manufactured in accordance with national provisions in force upon adoption of this Directive, including those implementing the Convention of 1 July 1969 on the Reciprocal Recognition of Proofmarks on Small Arms. Such transitional arrangements will also enable the European standardisation organisations to draft standards ensuring the safety level based on the state of the art.

(7) This Directive does not apply to the lifting of persons by means of machines not designed for the lifting of persons. However, this does not affect the right of Member States to take national measures, in accordance with the Treaty, with respect to such machines, with a view to implementing Council Directive 89/655/EEC of 30 November 1989 concerning the minimum safety and health requirements for the use of work equipment by workers at work (second individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC (7)).

(8) In relation to agricultural and forestry tractors, the provisions of this Directive concerning the risks currently not covered by Directive 2003/37/EC of the European Parliament and of the Council of 26 May 2003 on type-approval of agricultural or forestry tractors, their trailers and interchangeable towed machinery, together with their systems, components and separate technical units (1) should no longer apply when such risks are covered by Directive 2003/37/EC.

(9) Market surveillance is an essential instrument inasmuch as it ensures the proper and uniform application of Directives. It is therefore appropriate to put in place the legal framework within which market surveillance can proceed harmoniously.

(10) Member States are responsible for ensuring that this Directive is effectively enforced on their territory and that the safety of the machinery concerned is, as far as possible, improved in accordance with its provisions. Member States should ensure their capacity to carry out effective market surveillance, taking account of guidelines developed by the Commission, in order to achieve the proper and uniform application of this Directive.

(11) In the context of market surveillance, a clear distinction should be established between the disputing of a harmonised standard conferring a presumption of conformity on machinery and the safeguard clause relating to machinery.

(12) The putting into service of machinery within the meaning of this Directive can relate only to the use of the machinery itself for its intended purpose or for a purpose which can reasonably be foreseen. This does not preclude the laying down of conditions of use external to the machinery, provided that it is not thereby modified in a way not specified in this Directive.

(13) It is also necessary to provide for an adequate mechanism allowing for the adoption of specific measures at Community level requiring Member States to prohibit or restrict the placing on the market of certain types of machinery presenting the same risks to the health and safety of persons either due to shortcomings in the relevant harmonised standard(s) or by virtue of their technical characteristics, or to make such machinery subject to special conditions. In order to ensure the appropriate assessment of the need for such measures, they should be taken by the Commission, assisted by a committee, in the light of consultations with the Member States and other interested parties. Since such measures are not directly applicable to economic operators, Member States should take all necessary measures for their implementation.

(14) The essential health and safety requirements should be satisfied in order to ensure that machinery is safe; these requirements should be applied with discernment to take account of the state of the art at the time of construction and of technical and economic requirements.

(15) Where the machinery may be used by a consumer, that is to say, a non-professional operator, the manufacturer should take account of this in the design and construction. The same applies where a machine is normally used to provide a service to a consumer.

(16) Although the requirements of this Directive do not apply to partly completed machinery in their entirety, it is nevertheless important that the free movement of such machinery be guaranteed by means of a specific procedure.

(17) For trade fairs, exhibitions and such like, it should be possible to exhibit machinery which does not satisfy the requirements of this Directive. However, interested parties should be properly informed that the machinery does not conform and cannot be purchased in that condition.

(18) This Directive defines only the essential health and safety requirements of general application, supplemented by a number of more specific requirements for certain categories of machinery. In order to help manufacturers to prove conformity to these essential requirements, and to allow inspection of conformity to the essential requirements, it is desirable to have standards that are harmonised at Community level for the prevention of risks arising out of the design and construction of machinery. These standards are drawn up by private-law bodies and should retain their non-binding status.

(19) In view of the nature of the risks involved in the use of machinery covered by this Directive, procedures for assessing conformity to the essential health and safety requirements should be established. These procedures should be devised in the light of the extent of the danger inherent in such machinery. Consequently, each category of machinery should have its appropriate procedure in conformity with Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives (2), taking account of the nature of the verification required for such machinery.


(20) Manufacturers should retain full responsibility for certifying the conformity of their machinery to the provisions of this Directive. Nevertheless, for certain types of machinery having a higher risk factor, a stricter certification procedure is desirable.

(21) The CE marking should be fully recognised as being the only marking which guarantees that machinery conforms to the requirements of this Directive. All other markings which are likely to mislead third parties as to the meaning or the form of the CE marking, or both, should be prohibited.

(22) In order to ensure the same quality for the CE marking and the manufacturer's mark, it is important that they be affixed according to the same techniques. In order to avoid confusion between any CE markings which might appear on certain components and the CE marking corresponding to the machinery, it is important that the latter marking be affixed alongside the name of the person who has taken responsibility for it, namely the manufacturer or his authorised representative.

(23) The manufacturer or his authorised representative should also ensure that a risk assessment is carried out for the machinery which he wishes to place on the market. For this purpose, he should determine which are the essential health and safety requirements applicable to his machinery and in respect of which he must take measures.

(24) It is essential that, before drawing up the EC declaration of conformity, the manufacturer or his authorised representative established in the Community should prepare a technical construction file. However, it is not essential that all documentation should be permanently available in material form, but it must be possible to make it available on request. It need not include detailed plans of subassemblies used for the manufacture of machinery, unless knowledge of such plans is essential in order to ascertain conformity with the essential health and safety requirements.

(25) The addressees of any decision taken under this Directive should be informed of the reasons for such a decision and of the legal remedies open to them.

(26) Member States should provide for penalties applicable to infringements of the provisions of this Directive. Those penalties should be effective, proportionate and dissuasive.


(28) Since the objective of this Directive, namely, to lay down the essential health and safety requirements in relation to design and manufacture in order to improve the safety of machinery placed on the market, cannot be sufficiently achieved by the Member States and can be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.

(29) In accordance with point 34 of the Interinstitutional Agreement on better law-making (2), Member States are encouraged to draw up, for themselves and in the interests of the Community, their own tables illustrating, as far as possible, the correlation between this Directive and the transposition measures, and to make them public.

(30) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (3).

HAS ADOPTED THIS DIRECTIVE:

Article 1

Scope

1. This Directive applies to the following products:

(a) machinery;
(b) interchangeable equipment;
(c) safety components;
(d) lifting accessories;
(e) chains, ropes and webbing;
(f) removable mechanical transmission devices;
(g) partly completed machinery.

The following are excluded from the scope of this Directive:

(a) safety components intended to be used as spare parts to replace identical components and supplied by the manufacturer of the original machinery;

(b) specific equipment for use in fairgrounds and/or amusement parks;

(c) machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity;

(d) weapons, including firearms;

(e) the following means of transport:

— agricultural and forestry tractors for the risks covered by Directive 2003/37/EC, with the exclusion of machinery mounted on these vehicles,


— vehicles covered by Directive 2002/24/EC of the European Parliament and of the Council of 18 March 2002 relating to the type-approval of two or three-wheel motor vehicles (2), with the exclusion of machinery mounted on these vehicles,

— motor vehicles exclusively intended for competition, and

— means of transport by air, on water and on rail networks with the exclusion of machinery mounted on these means of transport;

(f) seagoing vessels and mobile offshore units and machinery installed on board such vessels and/or units;

(g) machinery specially designed and constructed for military or police purposes;

(h) machinery specially designed and constructed for research purposes for temporary use in laboratories;

(i) mine winding gear;

(j) machinery intended to move performers during artistic performances;

(k) electrical and electronic products falling within the following areas, insofar as they are covered by Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (4):

— household appliances intended for domestic use,

— audio and video equipment,

— information technology equipment,

— ordinary office machinery,

— low-voltage switchgear and control gear,

— electric motors;

(l) the following types of high-voltage electrical equipment:

— switch gear and control gear,

— transformers.

Article 2

Definitions

For the purposes of this Directive, ‘machinery’ designates the products listed in Article 1(1)(a) to (f).

The following definitions shall apply:

(a) ‘machinery’ means:

— an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application,

— an assembly referred to in the first indent, missing only the components to connect it on site or to sources of energy and motion,

— an assembly referred to in the first and second indents, ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure,

— assemblies of machinery referred to in the first, second and third indents or partly completed machinery referred to in point (g) which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole,

— an assembly of linked parts or components, at least one of which moves and which are joined together, intended for lifting loads and whose only power source is directly applied human effort;


(b) ‘interchangeable equipment’ means a device which, after the putting into service of machinery or of a tractor, is assembled with that machinery or tractor by the operator himself in order to change its function or attribute a new function, in so far as this equipment is not a tool;

(c) ‘safety component’ means a component:

— which serves to fulfil a safety function,

— which is independently placed on the market,

— the failure and/or malfunction of which endangers the safety of persons, and

— which is not necessary in order for the machinery to function, or for which normal components may be substituted in order for the machinery to function.

An indicative list of safety components is set out in Annex V, which may be updated in accordance with Article 8(1)(a);

(d) ‘lifting accessory’ means a component or equipment not attached to the lifting machinery, allowing the load to be held, which is placed between the machinery and the load or on the load itself, or which is intended to constitute an integral part of the load and which is independently placed on the market; slings and their components are also regarded as lifting accessories;

(e) ‘chains, ropes and webbing’ means chains, ropes and webbing designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;

(f) ‘removable mechanical transmission device’ means a removable component for transmitting power between self-propelled machinery or a tractor and another machine by joining them at the first fixed bearing. When it is placed on the market with the guard it shall be regarded as one product;

(g) ‘partly completed machinery’ means an assembly which is almost machinery but which cannot in itself perform a specific application. A drive system is partly completed machinery. Partly completed machinery is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Directive applies;

(h) ‘placing on the market’ means making available for the first time in the Community machinery or partly completed machinery with a view to distribution or use, whether for reward or free of charge;

(i) ‘manufacturer’ means any natural or legal person who designs and/or manufactures machinery or partly completed machinery covered by this Directive and is responsible for the conformity of the machinery or the partly completed machinery with this Directive with a view to its being placed on the market, under his own name or trademark or for his own use. In the absence of a manufacturer as defined above, any natural or legal person who places on the market or puts into service machinery or partly completed machinery covered by this Directive shall be considered a manufacturer;

(j) ‘authorised representative’ means any natural or legal person established in the Community who has received a written mandate from the manufacturer to perform on his behalf all or part of the obligations and formalities connected with this Directive;

(k) ‘putting into service’ means the first use, for its intended purpose, in the Community, of machinery covered by this Directive;

(l) ‘harmonised standard’ means a non-binding technical specification adopted by a standardisation body, namely the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) or the European Telecommunications Standards Institute (ETSI), on the basis of a remit issued by the Commission in accordance with the procedures laid down in Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services (1).

**Article 3**

**Specific Directives**

Where, for machinery, the hazards referred to in Annex I are wholly or partly covered more specifically by other Community Directives, this Directive shall not apply, or shall cease to apply, to that machinery in respect of such hazards from the date of implementation of those other Directives.

**Article 4**

**Market surveillance**

1. Member States shall take all appropriate measures to ensure that machinery may be placed on the market and/or put into service only if it satisfies the relevant provisions of this Directive and does not endanger the health and safety of persons and, where appropriate, domestic animals or property, when properly installed and maintained and used for its intended purpose or under conditions which can reasonably be foreseen.

2. Member States shall take all appropriate measures to ensure that partly completed machinery can be placed on the market only if it satisfies the relevant provisions of this Directive.

3. Member States shall institute or appoint the competent authorities to monitor the conformity of machinery and partly completed machinery with the provisions set out in paragraphs 1 and 2.

4. Member States shall define the tasks, organisation and powers of the competent authorities referred to in paragraph 3 and shall notify the Commission and other Member States thereof and also of any subsequent amendment.

**Article 5**

**Placing on the market and putting into service**

1. Before placing machinery on the market and/or putting it into service, the manufacturer or his authorised representative shall:

   (a) ensure that it satisfies the relevant essential health and safety requirements set out in Annex I;

   (b) ensure that the technical file referred to in Annex VII, part A is available;

   (c) provide, in particular, the necessary information, such as instructions;

   (d) carry out the appropriate procedures for assessing conformity in accordance with Article 12;

   (e) draw up the EC declaration of conformity in accordance with Annex II, part 1. Section A and ensure that it accompanies the machinery;

   (f) affix the CE marking in accordance with Article 16.

2. Before placing partly completed machinery on the market, the manufacturer or his authorised representative shall ensure that the procedure referred to in Article 13 has been completed.

3. For the purposes of the procedures referred to in Article 12, the manufacturer or his authorised representative shall have, or shall have access to, the necessary means of ensuring that the machinery satisfies the essential health and safety requirements set out in Annex I.

4. Where machinery is also the subject of other Directives relating to other aspects and providing for the affixing of the CE marking, the marking shall indicate that the machinery also conforms to the provisions of those other Directives.

However, where one or more of those Directives allow the manufacturer or his authorised representative to choose, during a transitional period, the system to be applied, the CE marking shall indicate conformity only to the provisions of those Directives applied by the manufacturer or his authorised representative. Particulars of the Directives applied, as published in the *Official Journal of the European Union*, shall be given on the EC declaration of conformity.

**Article 6**

**Freedom of movement**

1. Member States shall not prohibit, restrict or impede the placing on the market and/or putting into service in their territory of machinery which complies with this Directive.

2. Member States shall not prohibit, restrict or impede the placing on the market of partly completed machinery where the manufacturer or his authorised representative makes a declaration of incorporation, referred to in Annex II, part 1. Section B, stating that it is to be incorporated into machinery or assembled with other partly completed machinery to form machinery.

3. At trade fairs, exhibitions, demonstrations, and such like, Member States shall not prevent the showing of machinery or partly completed machinery which does not conform to this Directive, provided that a visible sign clearly indicates that it does not conform and that it will not be made available until it has been brought into conformity. Furthermore, during demonstrations of such non-conforming machinery or partly completed machinery, adequate safety measures shall be taken to ensure the protection of persons.

**Article 7**

**Presumption of conformity and harmonised standards**

1. Member States shall regard machinery bearing the CE marking and accompanied by the EC declaration of conformity, the content of which is set out in Annex II, part 1. Section A, as complying with the provisions of this Directive.

2. Machinery manufactured in conformity with a harmonised standard, the references to which have been published in the *Official Journal of the European Union*, shall be presumed to comply with the essential health and safety requirements covered by such a harmonised standard.

3. The Commission shall publish in the *Official Journal of the European Union* the references of the harmonised standards.

4. Member States shall take the appropriate measures to enable the social partners to have an influence at national level on the process of preparing and monitoring the harmonised standards.
Article 8

Specific measures

1. The Commission, acting in accordance with the procedure referred to in Article 22(3), may take any appropriate measure to implement the provisions relating to the following points:

(a) updating of the indicative list of safety components in Annex V referred to in point (c) in Article 2;

(b) restriction of the placing on the market of machinery referred to in Article 9.

2. The Commission, acting in accordance with the procedure referred to in Article 22(2), may take any appropriate measure connected with the implementation and practical application of this Directive, including measures necessary to ensure cooperation of Member States with each other and with the Commission, as provided for in Article 19(1).

Article 9

Specific measures to deal with potentially hazardous machinery

1. When, in accordance with the procedure referred to in Article 10, the Commission considers that a harmonised standard does not entirely satisfy the essential health and safety requirements which it covers and which are set out in Annex I, the Commission may, in accordance with paragraph 3 of this Article, take measures requiring Member States to prohibit or restrict the placing on the market of machinery with technical characteristics presenting risks due to the shortcomings in the standard or to make such machinery subject to special conditions.

When, in accordance with the procedure referred to in Article 11, the Commission considers that a measure taken by a Member State is justified, the Commission may, in accordance with paragraph 3 of this Article, take measures requiring Member States to prohibit or restrict the placing on the market of machinery presenting the same risk by virtue of its technical characteristics or to make such machinery subject to special conditions.

2. Any Member State may request the Commission to examine the need for the adoption of the measures referred to in paragraph 1.

3. In the cases referred to in paragraph 1, the Commission shall consult the Member States and other interested parties indicating the measures it intends to take, in order to ensure, at Community level, a high level of protection of the health and safety of persons.

Taking due account of the results of this consultation, it shall adopt the necessary measures in accordance with the procedure referred to in Article 22(3).

Article 10

Procedure for disputing a harmonised standard

Where a Member State or the Commission considers that a harmonised standard does not entirely satisfy the essential health and safety requirements which it covers and which are set out in Annex I, the Commission or the Member State shall bring the matter before the committee set up by Directive 98/34/EC, setting out the reasons therefor. The committee shall deliver an opinion without delay. In the light of the committee's opinion, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in the Official Journal of the European Union.

Article 11

Safeguard clause

1. Where a Member State ascertains that machinery covered by this Directive, bearing the CE marking, accompanied by the EC declaration of conformity and used in accordance with its intended purpose or under conditions which can reasonably be foreseen, is liable to compromise the health and safety of persons and, where appropriate, domestic animals or property, it shall take all appropriate measures to withdraw such machinery from the market, to prohibit the placing on the market and/or putting into service of such machinery or to restrict free movement thereof.

2. The Member State shall immediately inform the Commission and the other Member States of any such measure, indicating the reasons for its decision and, in particular, whether the non-conformity is due to:

(a) failure to satisfy the essential requirements referred to in Article 5(1)(a);

(b) incorrect application of the harmonised standards referred to in Article 7(2);

(c) shortcomings in the harmonised standards themselves referred to in Article 7(2).

3. The Commission shall enter into consultation with the parties concerned without delay.

The Commission shall consider, after this consultation, whether or not the measures taken by the Member State are justified, and it shall communicate its decision to the Member State which took the initiative, the other Member States, and the manufacturer or his authorised representative.
4. Where the measures referred to in paragraph 1 are based on a shortcoming in the harmonised standards and if the Member State which instigated the measures maintains its position, the Commission or the Member State shall initiate the procedure referred to in Article 10.

5. Where machinery does not conform and bears the CE marking, the competent Member State shall take appropriate action against whomsoever has affixed the marking and shall so inform the Commission. The Commission shall inform the other Member States.

6. The Commission shall ensure that Member States are kept informed of the progress and outcome of the procedure.

Article 12

Procedures for assessing the conformity of machinery

1. The manufacturer or his authorised representative shall, in order to certify the conformity of machinery with the provisions of this Directive, apply one of the procedures for assessment of conformity described in paragraphs 2, 3 and 4.

2. Where the machinery is not referred to in Annex IV, the manufacturer or his authorised representative shall apply the procedure for assessment of conformity with internal checks on the manufacture of machinery provided for in Annex VIII.

3. Where the machinery is referred to in Annex IV and manufactured in accordance with the harmonised standards referred to in Article 7(2), and provided that those standards cover all of the relevant essential health and safety requirements, the manufacturer or his authorised representative shall apply one of the following procedures:

(a) the procedure for assessment of conformity with internal checks on the manufacture of machinery, provided for in Annex VIII;

(b) the EC type-examination procedure provided for in Annex IX, plus the internal checks on the manufacture of machinery provided for in Annex VIII, point 3;

(c) the full quality assurance procedure provided for in Annex X.

4. Where the machinery is referred to in Annex IV and has not been manufactured in accordance with the harmonised standards referred to in Article 7(2), or only partly in accordance with such standards, or if the harmonised standards do not cover all the relevant essential health and safety requirements or if no harmonised standards exist for the machinery in question, the manufacturer or his authorised representative shall apply one of the following procedures:

(a) the EC type-examination procedure provided for in Annex IX, plus the internal checks on the manufacture of machinery provided for in Annex VIII, point 3;

(b) the full quality assurance procedure provided for in Annex X.

Article 13

Procedure for partly completed machinery

1. The manufacturer of partly completed machinery or his authorised representative shall, before placing it on the market, ensure that:

(a) the relevant technical documentation described in Annex VII, part B is prepared;

(b) assembly instructions described in Annex VI are prepared;

(c) a declaration of incorporation described in Annex II, part 1, Section B has been drawn up.

2. The assembly instructions and the declaration of incorporation shall accompany the partly completed machinery until it is incorporated into the final machinery and shall then form part of the technical file for that machinery.

Article 14

Notified bodies

1. Member States shall notify the Commission and the other Member States of the bodies which they have appointed to carry out the assessment of conformity for placing on the market referred to in Article 12(3) and (4), together with the specific conformity assessment procedures and categories of machinery for which these bodies have been appointed and the identification numbers assigned to them beforehand by the Commission. Member States shall notify the Commission and other Member States of any subsequent amendment.

2. The Member States shall ensure that the notified bodies are monitored regularly to check that they comply at all times with the criteria set out in Annex XI. The notified body shall provide all relevant information on request, including budgetary documents, to enable the Member States to ensure that the requirements of Annex XI are met.

3. Member States shall apply the criteria set out in Annex XI in assessing the bodies to be notified and the bodies already notified.
4. The Commission shall publish in the Official Journal of the European Union, for information, a list of the notified bodies and their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date.

5. Bodies meeting the assessment criteria laid down in the relevant harmonised standards, the references of which shall be published in the Official Journal of the European Union, shall be presumed to fulfil the relevant criteria.

6. If a notified body finds that relevant requirements of this Directive have not been met or are no longer met by the manufacturer or that an EC type-examination certificate or the approval of a quality assurance system should not have been issued, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate or the approval issued or place restrictions on it, giving detailed reasons, unless compliance with such requirements is ensured by the implementation of appropriate corrective measures by the manufacturer. In the event of suspension or withdrawal of the certificate or the approval or of any restriction placed on it, or in cases where intervention by the competent authority may prove necessary, the notified body shall inform the competent authority pursuant to Article 4. The Member State shall inform the other Member States and the Commission without delay. An appeal procedure shall be available.

7. The Commission shall provide for the organisation of an exchange of experience between the authorities responsible for appointment, notification and monitoring of notified bodies in the Member States, and the notified bodies, in order to coordinate the uniform application of this Directive.

8. A Member State which has notified a body shall immediately withdraw its notification if it finds:

(a) that the body no longer meets the criteria set out in Annex XI; or

(b) that the body seriously fails to fulfil its responsibilities.

The Member State shall immediately inform the Commission and the other Member States accordingly.

Article 15

Installation and use of machinery

This Directive shall not affect Member States’ entitlement to lay down, in due observance of Community law, such require-
ments as they may deem necessary to ensure that persons, and in particular workers, are protected when using machinery, provided that this does not mean that such machinery is modified in a way not specified in this Directive.

Article 16

CE marking

1. The CE conformity marking shall consist of the initials ‘CE’ as shown in Annex III.

2. The CE marking shall be affixed to the machinery visibly, legibly and indelibly in accordance with Annex III.

3. The affixing on machinery of markings, signs and inscriptions which are likely to mislead third parties as to the meaning or form of the CE marking, or both, shall be prohibited. Any other marking may be affixed to the machinery provided that the visibility, legibility and meaning of the CE marking is not thereby impaired.

Article 17

Non-conformity of marking

1. Member States shall consider the following marking not to conform:

(a) the affixing of the CE marking pursuant to this Directive on products not covered by this Directive;

(b) the absence of the CE marking and/or the absence of the EC declaration of conformity for machinery;

(c) the affixing on machinery of a marking, other than the CE marking, which is prohibited under Article 16(3).

2. Where a Member State ascertains that marking does not conform to the relevant provisions of this Directive, the manufacturer or his authorised representative shall be obliged to make the product conform and to put an end to the infringement under conditions fixed by that Member State.

3. Where non-conformity persists, the Member State shall take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market in accordance with the procedure laid down in Article 11.
Article 18

Confidentiality

1. Without prejudice to existing national provisions and practices in the area of confidentiality, Members States shall ensure that all parties and persons concerned by the application of this Directive are required to treat as confidential information obtained in the execution of their tasks. More particularly business, professional and trade secrets shall be treated as confidential, unless the divulging of such information is necessary in order to protect the health and safety of persons.

2. The provisions of paragraph 1 shall not affect the obligations of the Member States and the notified bodies with regard to mutual exchange of information and the issuing of warnings.

3. Any decisions taken by the Member States and the Commission in accordance with Articles 9 and 11 shall be published.

Article 19

Cooperation between Member States

1. Member States shall take the appropriate measures to ensure that the competent authorities referred to in Article 4(3) cooperate with each other and with the Commission and transmit to each other the information necessary to enable this Directive to be applied uniformly.

2. The Commission shall provide for the organisation of an exchange of experience between the competent authorities responsible for market surveillance in order to coordinate the uniform application of this Directive.

Article 20

Legal remedies

Any measure taken pursuant to this Directive which restricts the placing on the market and/or putting into service of any machinery covered by this Directive shall state the exact grounds on which it is based. Such a measure shall be notified as soon as possible to the party concerned, who shall at the same time be informed of the legal remedies available to him under the laws in force in the Member State concerned and of the time limits to which such remedies are subject.

Article 21

Dissemination of information

The Commission shall take the necessary measures for appropriate information concerning the implementation of this Directive to be made available.

Article 22

Committee

1. The Commission shall be assisted by a committee, hereinafter referred to as the ‘Committee’.

2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

4. The Committee shall adopt its rules of procedure.

Article 23

Penalties

Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 29 June 2008 and shall notify it without delay of any subsequent amendment affecting them.

Article 24

Amendment of Directive 95/16/EC

Directive 95/16/EC is hereby amended as follows:

1. in Article 1, paragraphs 2 and 3 shall be replaced by the following:

2. For the purposes of this Directive, “lift” shall mean a lifting appliance serving specific levels, having a carrier moving along guides which are rigid and inclined at an angle of more than 15 degrees to the horizontal, intended for the transport of:

— persons,
— persons and goods,
— goods alone if the carrier is accessible, that is to say a person may enter it without difficulty, and fitted with controls situated inside the carrier or within reach of a person inside the carrier.

Lifting appliances moving along a fixed course even where they do not move along guides which are rigid shall be considered as lifts falling within the scope of this Directive.
A “carrier” means a part of the lift by which persons and/or goods are supported in order to be lifted or lowered.

3. This Directive shall not apply to:
— lifting appliances whose speed is not greater than 0.15 m/s,
— construction site hoists,
— cableways, including funicular railways,
— lifts specially designed and constructed for military or police purposes,
— lifting appliances from which work can be carried out,
— mine winding gear,
— lifting appliances intended for lifting performers during artistic performances,
— lifting appliances fitted in means of transport,
— lifting appliances connected to machinery and intended exclusively for access to workstations including maintenance and inspection points on the machinery,
— rack and pinion trains,
— escalators and mechanical walkways;

2. in Annex I, point 1.2 shall be replaced by the following:

1.2. ‘Carrier

The carrier of each lift must be a car. This car must be designed and constructed to offer the space and strength corresponding to the maximum number of persons and the rated load of the lift set by the installer.

Where the lift is intended for the transport of persons, and where its dimensions permit, the car must be designed and constructed in such a way that its structural features do not obstruct or impede access and use by disabled persons and so as to allow any appropriate adjustments intended to facilitate its use by them.’

Article 25

Repeal

Directive 98/37/EC is hereby repealed.

References made to the repealed Directive shall be construed as being made to this Directive and should be read in accordance with the correlation table in Annex XII.

Article 26

Transposition

1. Member States shall adopt and publish the provisions necessary to comply with this Directive by 29 June 2008 at the latest. They shall forthwith inform the Commission thereof.

They shall apply those provisions with effect from 29 December 2009.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the provisions of national law which they adopt in the field covered by this Directive, together with a table showing how the provisions of this Directive correspond to the national provisions adopted.

Article 27

Derogation

Until 29 June 2011 Member States may allow the placing on the market and the putting into service of portable cartridge-operated fixing and other impact machinery which are in conformity with the national provisions in force upon adoption of this Directive.

Article 28

Entry into force

This Directive shall enter into force on the 20th day following its publication in the Official Journal of the European Union.

Article 29

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 17 May 2006.

For the European Parliament

J. BORRELL FONTELLES

For the Council

The President

H. WINKLER
ANNEX I

Essential health and safety requirements relating to the design and construction of machinery

GENERAL PRINCIPLES

1. The manufacturer of machinery or his authorised representative must ensure that a risk assessment is carried out in order to determine the health and safety requirements which apply to the machinery. The machinery must then be designed and constructed taking into account the results of the risk assessment.

By the iterative process of risk assessment and risk reduction referred to above, the manufacturer or his authorised representative shall:

— determine the limits of the machinery, which include the intended use and any reasonably foreseeable misuse thereof,

— identify the hazards that can be generated by the machinery and the associated hazardous situations,

— estimate the risks, taking into account the severity of the possible injury or damage to health and the probability of its occurrence,

— evaluate the risks, with a view to determining whether risk reduction is required, in accordance with the objective of this Directive,

— eliminate the hazards or reduce the risks associated with these hazards by application of protective measures, in the order of priority established in section 1.1.2(b).

2. The obligations laid down by the essential health and safety requirements only apply when the corresponding hazard exists for the machinery in question when it is used under the conditions foreseen by the manufacturer or his authorised representative or in foreseeable abnormal situations. In any event, the principles of safety integration referred to in section 1.1.2 and the obligations concerning marking of machinery and instructions referred to in sections 1.7.3 and 1.7.4 apply.

3. The essential health and safety requirements laid down in this Annex are mandatory; However, taking into account the state of the art, it may not be possible to meet the objectives set by them. In that event, the machinery must, as far as possible, be designed and constructed with the purpose of approaching these objectives.

4. This Annex is organised in several parts. The first one has a general scope and is applicable to all kinds of machinery. The other parts refer to certain kinds of more specific hazards. Nevertheless, it is essential to examine the whole of this Annex in order to be sure of meeting all the relevant essential requirements. When machinery is being designed, the requirements of the general part and the requirements of one or more of the other parts shall be taken into account, depending on the results of the risk assessment carried out in accordance with point 1 of these General Principles.

1. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

1.1. GENERAL REMARKS

1.1.1. Definitions

For the purpose of this Annex:

(a) ‘hazard’ means a potential source of injury or damage to health;

(b) ‘danger zone’ means any zone within and/or around machinery in which a person is subject to a risk to his health or safety;

(c) ‘exposed person’ means any person wholly or partially in a danger zone;

(d) ‘operator’ means the person or persons installing, operating, adjusting, maintaining, cleaning, repairing or moving machinery;

(e) ‘risk’ means a combination of the probability and the degree of an injury or damage to health that can arise in a hazardous situation;

(f) ‘guard’ means a part of the machinery used specifically to provide protection by means of a physical barrier;

(g) ‘protective device’ means a device (other than a guard) which reduces the risk, either alone or in conjunction with a guard;

(h) ‘intended use’ means the use of machinery in accordance with the information provided in the instructions for use;

(i) ‘reasonably foreseeable misuse’ means the use of machinery in a way not intended in the instructions for use, but which may result from readily predictable human behaviour.
1.1.2. **Principles of safety integration**

(a) Machinery must be designed and constructed so that it is fitted for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen but also taking into account any reasonably foreseeable misuse thereof.

The aim of measures taken must be to eliminate any risk throughout the foreseeable lifetime of the machinery including the phases of transport, assembly, dismantling, disabling and scrapping.

(b) In selecting the most appropriate methods, the manufacturer or his authorised representative must apply the following principles, in the order given:

— eliminate or reduce risks as far as possible (inherently safe machinery design and construction),

— take the necessary protective measures in relation to risks that cannot be eliminated,

— inform users of the residual risks due to any shortcomings of the protective measures adopted, indicate whether any particular training is required and specify any need to provide personal protective equipment.

(c) When designing and constructing machinery and when drafting the instructions, the manufacturer or his authorised representative must envisage not only the intended use of the machinery but also any reasonably foreseeable misuse thereof.

The machinery must be designed and constructed in such a way as to prevent abnormal use if such use would engender a risk. Where appropriate, the instructions must draw the user's attention to ways — which experience has shown might occur — in which the machinery should not be used.

(d) Machinery must be designed and constructed to take account of the constraints to which the operator is subject as a result of the necessary or foreseeable use of personal protective equipment.

(e) Machinery must be supplied with all the special equipment and accessories essential to enable it to be adjusted, maintained and used safely.

1.1.3. **Materials and products**

The materials used to construct machinery or products used or created during its use must not endanger persons’ safety or health. In particular, where fluids are used, machinery must be designed and constructed to prevent risks due to filling, use, recovery or draining.

1.1.4. **Lighting**

Machinery must be supplied with integral lighting suitable for the operations concerned where the absence thereof is likely to cause a risk despite ambient lighting of normal intensity.

Machinery must be designed and constructed so that there is no area of shadow likely to cause nuisance, that there is no irritating dazzle and that there are no dangerous stroboscopic effects on moving parts due to the lighting.

Internal parts requiring frequent inspection and adjustment, and maintenance areas must be provided with appropriate lighting.

1.1.5. **Design of machinery to facilitate its handling**

Machinery, or each component part thereof, must:

— be capable of being handled and transported safely.

— be packaged or designed so that it can be stored safely and without damage.

During the transportation of the machinery and/or its component parts, there must be no possibility of sudden movements or of hazards due to instability as long as the machinery and/or its component parts are handled in accordance with the instructions.

Where the weight, size or shape of machinery or its various component parts prevents them from being moved by hand, the machinery or each component part must:

— either be fitted with attachments for lifting gear, or

— be designed so that it can be fitted with such attachments, or

— be shaped in such a way that standard lifting gear can easily be attached.
Where machinery or one of its component parts is to be moved by hand, it must:

— either be easily moveable, or
— be equipped for picking up and moving safely.

Special arrangements must be made for the handling of tools and/or machinery parts which, even if light-weight, could be hazardous.

1.1.6. **Ergonomics**

Under the intended conditions of use, the discomfort, fatigue and physical and psychological stress faced by the operator must be reduced to the minimum possible, taking into account ergonomic principles such as:

— allowing for the variability of the operator's physical dimensions, strength and stamina,
— providing enough space for movements of the parts of the operator's body,
— avoiding a machine-determined work rate,
— avoiding monitoring that requires lengthy concentration,
— adapting the man/machinery interface to the foreseeable characteristics of the operators.

1.1.7. **Operating positions**

The operating position must be designed and constructed in such a way as to avoid any risk due to exhaust gases and/or lack of oxygen.

If the machinery is intended to be used in a hazardous environment presenting risks to the health and safety of the operator or if the machinery itself gives rise to a hazardous environment, adequate means must be provided to ensure that the operator has good working conditions and is protected against any foreseeable hazards.

Where appropriate, the operating position must be fitted with an adequate cabin designed, constructed and/or equipped to fulfil the above requirements. The exit must allow rapid evacuation. Moreover, when applicable, an emergency exit must be provided in a direction which is different from the usual exit.

1.1.8. **Seating**

Where appropriate and where the working conditions so permit, work stations constituting an integral part of the machinery must be designed for the installation of seats.

If the operator is intended to sit during operation and the operating position is an integral part of the machinery, the seat must be provided with the machinery.

The operator's seat must enable him to maintain a stable position. Furthermore, the seat and its distance from the control devices must be capable of being adapted to the operator.

If the machinery is subject to vibrations, the seat must be designed and constructed in such a way as to reduce the vibrations transmitted to the operator to the lowest level that is reasonably possible. The seat mountings must withstand all stresses to which they can be subjected. Where there is no floor beneath the feet of the operator, footrests covered with a slip-resistant material must be provided.

1.2. **CONTROL SYSTEMS**

1.2.1. **Safety and reliability of control systems**

Control systems must be designed and constructed in such a way as to prevent hazardous situations from arising. Above all, they must be designed and constructed in such a way that:

— they can withstand the intended operating stresses and external influences,
— a fault in the hardware or the software of the control system does not lead to hazardous situations,
— errors in the control system logic do not lead to hazardous situations,
— reasonably foreseeable human error during operation does not lead to hazardous situations.
Particular attention must be given to the following points:

— the machinery must not start unexpectedly,

— the parameters of the machinery must not change in an uncontrolled way, where such change may lead to hazardous situations,

— the machinery must not be prevented from stopping if the stop command has already been given,

— no moving part of the machinery or piece held by the machinery must fall or be ejected,

— automatic or manual stopping of the moving parts, whatever they may be, must be unimpeded,

— the protective devices must remain fully effective or give a stop command,

— the safety-related parts of the control system must apply in a coherent way to the whole of an assembly of machinery and/or partly completed machinery.

For cable-less control, an automatic stop must be activated when correct control signals are not received, including loss of communication.

1.2.2. **Control devices**

Control devices must be:

— clearly visible and identifiable, using pictograms where appropriate,

— positioned in such a way as to be safely operated without hesitation or loss of time and without ambiguity,

— designed in such a way that the movement of the control device is consistent with its effect,

— located outside the danger zones, except where necessary for certain control devices such as an emergency stop or a teach pendant,

— positioned in such a way that their operation cannot cause additional risk,

— designed or protected in such a way that the desired effect, where a hazard is involved, can only be achieved by a deliberate action,

— made in such a way as to withstand foreseeable forces; particular attention must be paid to emergency stop devices liable to be subjected to considerable forces.

Where a control device is designed and constructed to perform several different actions, namely where there is no one-to-one correspondence, the action to be performed must be clearly displayed and subject to confirmation, where necessary.

Control devices must be so arranged that their layout, travel and resistance to operation are compatible with the action to be performed, taking account of ergonomic principles.

Machinery must be fitted with indicators as required for safe operation. The operator must be able to read them from the control position.

From each control position, the operator must be able to ensure that no-one is in the danger zones, or the control system must be designed and constructed in such a way that starting is prevented while someone is in the danger zone.

If neither of these possibilities is applicable, before the machinery starts, an acoustic and/or visual warning signal must be given. The exposed persons must have time to leave the danger zone or prevent the machinery starting up.

If necessary, means must be provided to ensure that the machinery can be controlled only from control positions located in one or more predetermined zones or locations.

Where there is more than one control position, the control system must be designed in such a way that the use of one of them precludes the use of the others, except for stop controls and emergency stops.

When machinery has two or more operating positions, each position must be provided with all the required control devices without the operators hindering or putting each other into a hazardous situation.
1.2.3. **Starting**

It must be possible to start machinery only by voluntary actuation of a control device provided for the purpose.

The same requirement applies:

— when restarting the machinery after a stoppage, whatever the cause,
— when effecting a significant change in the operating conditions.

However, the restarting of the machinery or a change in operating conditions may be effected by voluntary actuation of a device other than the control device provided for the purpose, on condition that this does not lead to a hazardous situation.

For machinery functioning in automatic mode, the starting of the machinery, restarting after a stoppage, or a change in operating conditions may be possible without intervention, provided this does not lead to a hazardous situation.

Where machinery has several starting control devices and the operators can therefore put each other in danger, additional devices must be fitted to rule out such risks. If safety requires that starting and/or stopping must be performed in a specific sequence, there must be devices which ensure that these operations are performed in the correct order.

1.2.4. **Stopping**

1.2.4.1. **Normal stop**

Machinery must be fitted with a control device whereby the machinery can be brought safely to a complete stop.

Each workstation must be fitted with a control device to stop some or all of the functions of the machinery, depending on the existing hazards, so that the machinery is rendered safe.

The machinery's stop control must have priority over the start controls.

Once the machinery or its hazardous functions have stopped, the energy supply to the actuators concerned must be cut off.

1.2.4.2. **Operational stop**

Where, for operational reasons, a stop control that does not cut off the energy supply to the actuators is required, the stop condition must be monitored and maintained.

1.2.4.3. **Emergency stop**

Machinery must be fitted with one or more emergency stop devices to enable actual or impending danger to be averted.

The following exceptions apply:

— machinery in which an emergency stop device would not lessen the risk, either because it would not reduce the stopping time or because it would not enable the special measures required to deal with the risk to be taken,
— portable hand-held and/or hand-guided machinery.

The device must:

— have clearly identifiable, clearly visible and quickly accessible control devices,
— stop the hazardous process as quickly as possible, without creating additional risks,
— where necessary, trigger or permit the triggering of certain safeguard movements.
Once active operation of the emergency stop device has ceased following a stop command, that command must be sustained by engagement of the emergency stop device until that engagement is specifically overridden; it must not be possible to engage the device without triggering a stop command; it must be possible to disengage the device only by an appropriate operation, and disengaging the device must not restart the machinery but only permit restarting.

The emergency stop function must be available and operational at all times, regardless of the operating mode.

Emergency stop devices must be a back-up to other safeguarding measures and not a substitute for them.

1.2.4.4. **Assembly of machinery**

In the case of machinery or parts of machinery designed to work together, the machinery must be designed and constructed in such a way that the stop controls, including the emergency stop devices, can stop not only the machinery itself but also all related equipment, if its continued operation may be dangerous.

1.2.5. **Selection of control or operating modes**

The control or operating mode selected must override all other control or operating modes, with the exception of the emergency stop.

If machinery has been designed and constructed to allow its use in several control or operating modes requiring different protective measures and/or work procedures, it must be fitted with a mode selector which can be locked in each position. Each position of the selector must be clearly identifiable and must correspond to a single operating or control mode.

The selector may be replaced by another selection method which restricts the use of certain functions of the machinery to certain categories of operator.

If, for certain operations, the machinery must be able to operate with a guard displaced or removed and/or a protective device disabled, the control or operating mode selector must simultaneously:

- disable all other control or operating modes,
- permit operation of hazardous functions only by control devices requiring sustained action,
- permit the operation of hazardous functions only in reduced risk conditions while preventing hazards from linked sequences,
- prevent any operation of hazardous functions by voluntary or involuntary action on the machine's sensors.

If these four conditions cannot be fulfilled simultaneously, the control or operating mode selector must activate other protective measures designed and constructed to ensure a safe intervention zone.

In addition, the operator must be able to control operation of the parts he is working on from the adjustment point.

1.2.6. **Failure of the power supply**

The interruption, the re-establishment after an interruption or the fluctuation in whatever manner of the power supply to the machinery must not lead to dangerous situations.

Particular attention must be given to the following points:

- the machinery must not start unexpectedly,
- the parameters of the machinery must not change in an uncontrolled way when such change can lead to hazardous situations,
- the machinery must not be prevented from stopping if the command has already been given,
— no moving part of the machinery or piece held by the machinery must fall or be ejected,
— automatic or manual stopping of the moving parts, whatever they may be, must be unimpeded,
— the protective devices must remain fully effective or give a stop command.

1.3. PROTECTION AGAINST MECHANICAL HAZARDS

1.3.1. Risk of loss of stability

Machinery and its components and fittings must be stable enough to avoid overturning, falling or uncontrolled movements during transportation, assembly, dismantling and any other action involving the machinery.

If the shape of the machinery itself or its intended installation does not offer sufficient stability, appropriate means of anchorage must be incorporated and indicated in the instructions.

1.3.2. Risk of break-up during operation

The various parts of machinery and their linkages must be able to withstand the stresses to which they are subject when used.

The durability of the materials used must be adequate for the nature of the working environment foreseen by the manufacturer or his authorised representative, in particular as regards the phenomena of fatigue, ageing, corrosion and abrasion.

The instructions must indicate the type and frequency of inspections and maintenance required for safety reasons. They must, where appropriate, indicate the parts subject to wear and the criteria for replacement.

Where a risk of rupture or disintegration remains despite the measures taken, the parts concerned must be mounted, positioned and/or guarded in such a way that any fragments will be contained, preventing hazardous situations.

Both rigid and flexible pipes carrying fluids, particularly those under high pressure, must be able to withstand the foreseen internal and external stresses and must be firmly attached and/or protected to ensure that no risk is posed by a rupture.

Where the material to be processed is fed to the tool automatically, the following conditions must be fulfilled to avoid risks to persons:
— when the workpiece comes into contact with the tool, the latter must have attained its normal working condition,
— when the tool starts and/or stops (intentionally or accidentally), the feed movement and the tool movement must be coordinated.

1.3.3. Risks due to falling or ejected objects

Precautions must be taken to prevent risks from falling or ejected objects.

1.3.4. Risks due to surfaces, edges or angles

Insofar as their purpose allows, accessible parts of the machinery must have no sharp edges, no sharp angles and no rough surfaces likely to cause injury.

1.3.5. Risks related to combined machinery

Where the machinery is intended to carry out several different operations with manual removal of the piece between each operation (combined machinery), it must be designed and constructed in such a way as to enable each element to be used separately without the other elements constituting a risk for exposed persons.

For this purpose, it must be possible to start and stop separately any elements that are not protected.

1.3.6. Risks related to variations in operating conditions

Where the machinery performs operations under different conditions of use, it must be designed and constructed in such a way that selection and adjustment of these conditions can be carried out safely and reliably.
1.3.7. **Risks related to moving parts**

The moving parts of machinery must be designed and constructed in such a way as to prevent risks of contact which could lead to accidents or must, where risks persist, be fitted with guards or protective devices.

All necessary steps must be taken to prevent accidental blockage of moving parts involved in the work. In cases where, despite the precautions taken, a blockage is likely to occur, the necessary specific protective devices and tools must, when appropriate, be provided to enable the equipment to be safely unblocked.

The instructions and, where possible, a sign on the machinery shall identify these specific protective devices and how they are to be used.

1.3.8. **Choice of protection against risks arising from moving parts**

Guards or protective devices designed to protect against risks arising from moving parts must be selected on the basis of the type of risk. The following guidelines must be used to help to make the choice.

1.3.8.1. **Moving transmission parts**

Guards designed to protect persons against the hazards generated by moving transmission parts must be:

— either fixed guards as referred to in section 1.4.2.1, or
— interlocking movable guards as referred to in section 1.4.2.2.

Interlocking movable guards should be used where frequent access is envisaged.

1.3.8.2. **Moving parts involved in the process**

Guards or protective devices designed to protect persons against the hazards generated by moving parts involved in the process must be:

— either fixed guards as referred to in section 1.4.2.1, or
— interlocking movable guards as referred to in section 1.4.2.2, or
— protective devices as referred to in section 1.4.3, or
— a combination of the above.

However, when certain moving parts directly involved in the process cannot be made completely inaccessible during operation owing to operations requiring operator intervention, such parts must be fitted with:

— fixed guards or interlocking movable guards preventing access to those sections of the parts that are not used in the work, and
— adjustable guards as referred to in section 1.4.2.3 restricting access to those sections of the moving parts where access is necessary.

1.3.9. **Risks of uncontrolled movements**

When a part of the machinery has been stopped, any drift away from the stopping position, for whatever reason other than action on the control devices, must be prevented or must be such that it does not present a hazard.

1.4. **REQUIRED CHARACTERISTICS OF GUARDS AND PROTECTIVE DEVICES**

1.4.1. **General requirements**

Guards and protective devices must:

— be of robust construction,
— be securely held in place,
— not give rise to any additional hazard,
— not be easy to by-pass or render non-operational,
— be located at an adequate distance from the danger zone,
— cause minimum obstruction to the view of the production process, and
— enable essential work to be carried out on the installation and/or replacement of tools and for maintenance purposes by restricting access exclusively to the area where the work has to be done, if possible without the guard having to be removed or the protective device having to be disabled.

In addition, guards must, where possible, protect against the ejection or falling of materials or objects and against emissions generated by the machinery.

1.4.2. **Special requirements for guards**

1.4.2.1. **Fixed guards**

Fixed guards must be fixed by systems that can be opened or removed only with tools.

Their fixing systems must remain attached to the guards or to the machinery when the guards are removed.

Where possible, guards must be incapable of remaining in place without their fixings.

1.4.2.2. **Interlocking movable guards**

Interlocking movable guards must:

— as far as possible remain attached to the machinery when open,
— be designed and constructed in such a way that they can be adjusted only by means of an intentional action.

Interlocking movable guards must be associated with an interlocking device that:

— prevents the start of hazardous machinery functions until they are closed and
— gives a stop command whenever they are no longer closed.

Where it is possible for an operator to reach the danger zone before the risk due to the hazardous machinery functions has ceased, movable guards must be associated with a guard locking device in addition to an interlocking device that:

— prevents the start of hazardous machinery functions until the guard is closed and locked, and
— keeps the guard closed and locked until the risk of injury from the hazardous machinery functions has ceased.

Interlocking movable guards must be designed in such a way that the absence or failure of one of their components prevents starting or stops the hazardous machinery functions.

1.4.2.3. **Adjustable guards restricting access**

Adjustable guards restricting access to those areas of the moving parts strictly necessary for the work must be:

— adjustable manually or automatically, depending on the type of work involved, and
— readily adjustable without the use of tools.

1.4.3. **Special requirements for protective devices**

Protective devices must be designed and incorporated into the control system in such a way that:

— moving parts cannot start up while they are within the operator’s reach,
— persons cannot reach moving parts while the parts are moving, and
— the absence or failure of one of their components prevents starting or stops the moving parts.

Protective devices must be adjustable only by means of an intentional action.

1.5. **RISKS DUE TO OTHER HAZARDS**

1.5.1. **Electricity supply**

Where machinery has an electricity supply, it must be designed, constructed and equipped in such a way that all hazards of an electrical nature are or can be prevented.

The safety objectives set out in Directive 73/23/EEC shall apply to machinery. However, the obligations concerning conformity assessment and the placing on the market and/or putting into service of machinery with regard to electrical hazards are governed solely by this Directive.

1.5.2. **Static electricity**

Machinery must be designed and constructed to prevent or limit the build-up of potentially dangerous electrostatic charges and/or be fitted with a discharging system.

1.5.3. **Energy supply other than electricity**

Where machinery is powered by source of energy other than electricity, it must be so designed, constructed and equipped as to avoid all potential risks associated with such sources of energy.

1.5.4. **Errors of fitting**

Errors likely to be made when fitting or refitting certain parts which could be a source of risk must be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information must be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.

Where necessary, the instructions must give further information on these risks.

Where a faulty connection can be the source of risk, incorrect connections must be made impossible by design or, failing this, by information given on the elements to be connected and, where appropriate, on the means of connection.

1.5.5. **Extreme temperatures**

Steps must be taken to eliminate any risk of injury arising from contact with or proximity to machinery parts or materials at high or very low temperatures.

The necessary steps must also be taken to avoid or protect against the risk of hot or very cold material being ejected.

1.5.6. **Fire**

Machinery must be designed and constructed in such a way as to avoid any risk of fire or overheating posed by the machinery itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery.

1.5.7. **Explosion**

Machinery must be designed and constructed in such a way as to avoid any risk of explosion posed by the machinery itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery.

Machinery must comply, as far as the risk of explosion due to its use in a potentially explosive atmosphere is concerned, with the provisions of the specific Community Directives.
1.5.8. **Noise**

Machinery must be designed and constructed in such a way that risks resulting from the emission of airborne noise are reduced to the lowest level, taking account of technical progress and the availability of means of reducing noise, in particular at source.

The level of noise emission may be assessed with reference to comparative emission data for similar machinery.

1.5.9. **Vibrations**

Machinery must be designed and constructed in such a way that risks resulting from vibrations produced by the machinery are reduced to the lowest level, taking account of technical progress and the availability of means of reducing vibration, in particular at source.

The level of vibration emission may be assessed with reference to comparative emission data for similar machinery.

1.5.10. **Radiation**

Undesirable radiation emissions from the machinery must be eliminated or be reduced to levels that do not have adverse effects on persons.

Any functional ionising radiation emissions must be limited to the lowest level which is sufficient for the proper functioning of the machinery during setting, operation and cleaning. Where a risk exists, the necessary protective measures must be taken.

Any functional non-ionising radiation emissions during setting, operation and cleaning must be limited to levels that do not have adverse effects on persons.

1.5.11. **External radiation**

Machinery must be designed and constructed in such a way that external radiation does not interfere with its operation.

1.5.12. **Laser radiation**

Where laser equipment is used, the following should be taken into account:

— laser equipment on machinery must be designed and constructed in such a way as to prevent any accidental radiation,

— laser equipment on machinery must be protected in such a way that effective radiation, radiation produced by reflection or diffusion and secondary radiation do not damage health,

— optical equipment for the observation or adjustment of laser equipment on machinery must be such that no health risk is created by laser radiation.

1.5.13. **Emissions of hazardous materials and substances**

Machinery must be designed and constructed in such a way that risks of inhalation, ingestion, contact with the skin, eyes and mucous membranes and penetration through the skin of hazardous materials and substances which it produces can be avoided.

Where a hazard cannot be eliminated, the machinery must be so equipped that hazardous materials and substances can be contained, evacuated, precipitated by water spraying, filtered or treated by another equally effective method.

Where the process is not totally enclosed during normal operation of the machinery, the devices for containment and/or evacuation must be situated in such a way as to have the maximum effect.

1.5.14. **Risk of being trapped in a machine**

Machinery must be designed, constructed or fitted with a means of preventing a person from being enclosed within it or, if that is impossible, with a means of summonsing help.
1.5.15. **Risk of slipping, tripping or falling**

Parts of the machinery where persons are liable to move about or stand must be designed and constructed in such a way as to prevent persons slipping, tripping or falling on or off these parts.

Where appropriate, these parts must be fitted with handholds that are fixed relative to the user and that enable them to maintain their stability.

1.5.16. **Lightning**

Machinery in need of protection against the effects of lightning while being used must be fitted with a system for conducting the resultant electrical charge to earth.

1.6. **MAINTENANCE**

1.6.1. **Machinery maintenance**

Adjustment and maintenance points must be located outside danger zones. It must be possible to carry out adjustment, maintenance, repair, cleaning and servicing operations while machinery is at a standstill.

If one or more of the above conditions cannot be satisfied for technical reasons, measures must be taken to ensure that these operations can be carried out safely (see section 1.2.5).

In the case of automated machinery and, where necessary, other machinery, a connecting device for mounting diagnostic fault-finding equipment must be provided.

Automated machinery components which have to be changed frequently must be capable of being removed and replaced easily and safely. Access to the components must enable these tasks to be carried out with the necessary technical means in accordance with a specified operating method.

1.6.2. **Access to operating positions and servicing points**

Machinery must be designed and constructed in such a way as to allow access in safety to all areas where intervention is necessary during operation, adjustment and maintenance of the machinery.

1.6.3. **Isolation of energy sources**

Machinery must be fitted with means to isolate it from all energy sources. Such isolators must be clearly identified. They must be capable of being locked if reconnection could endanger persons. Isolators must also be capable of being locked where an operator is unable, from any of the points to which he has access, to check that the energy is still cut off.

In the case of machinery capable of being plugged into an electricity supply, removal of the plug is sufficient, provided that the operator can check from any of the points to which he has access that the plug remains removed.

After the energy is cut off, it must be possible to dissipate normally any energy remaining or stored in the circuits of the machinery without risk to persons.

As an exception to the requirement laid down in the previous paragraphs, certain circuits may remain connected to their energy sources in order, for example, to hold parts, to protect information, to light interiors, etc. In this case, special steps must be taken to ensure operator safety.

1.6.4. **Operator intervention**

Machinery must be so designed, constructed and equipped that the need for operator intervention is limited. If operator intervention cannot be avoided, it must be possible to carry it out easily and safely.

1.6.5. **Cleaning of internal parts**

The machinery must be designed and constructed in such a way that it is possible to clean internal parts which have contained dangerous substances or preparations without entering them; any necessary unlocking must also be possible from the outside. If it is impossible to avoid entering the machinery, it must be designed and constructed in such a way as to allow cleaning to take place safely.
1.7. INFORMATION

1.7.1. Information and warnings on the machinery

Information and warnings on the machinery should preferably be provided in the form of readily understandable symbols or pictograms. Any written or verbal information and warnings must be expressed in an official Community language or languages, which may be determined in accordance with the Treaty by the Member State in which the machinery is placed on the market and/or put into service and may be accompanied, on request, by versions in any other official Community language or languages understood by the operators.

1.7.1.1. Information and information devices

The information needed to control machinery must be provided in a form that is unambiguous and easily understood. It must not be excessive to the extent of overloading the operator.

Visual display units or any other interactive means of communication between the operator and the machine must be easily understood and easy to use.

1.7.1.2. Warning devices

Where the health and safety of persons may be endangered by a fault in the operation of unsupervised machinery, the machinery must be equipped in such a way as to give an appropriate acoustic or light signal as a warning.

Where machinery is equipped with warning devices these must be unambiguous and easily perceived. The operator must have facilities to check the operation of such warning devices at all times.

The requirements of the specific Community Directives concerning colours and safety signals must be complied with.

1.7.2. Warning of residual risks

Where risks remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted, the necessary warnings, including warning devices, must be provided.

1.7.3. Marking of machinery

All machinery must be marked visibly, legibly and indelibly with the following minimum particulars:

— the business name and full address of the manufacturer and, where applicable, his authorised representative,
— designation of the machinery,
— the CE Marking (see Annex III),
— designation of series or type,
— serial number, if any,
— the year of construction, that is the year in which the manufacturing process is completed.

It is prohibited to pre-date or post-date the machinery when affixing the CE marking.

Furthermore, machinery designed and constructed for use in a potentially explosive atmosphere must be marked accordingly.

Machinery must also bear full information relevant to its type and essential for safe use. Such information is subject to the requirements set out in section 1.7.1.

Where a machine part must be handled during use with lifting equipment, its mass must be indicated legibly, indelibly and unambiguously.

1.7.4. Instructions

All machinery must be accompanied by instructions in the official Community language or languages of the Member State in which it is placed on the market and/or put into service.

The instructions accompanying the machinery must be either ‘Original instructions’ or a ‘Translation of the original instructions’, in which case the translation must be accompanied by the original instructions.
By way of exception, the maintenance instructions intended for use by specialised personnel mandated by the manufacturer or his authorised representative may be supplied in only one Community language which the specialised personnel understand.

The instructions must be drafted in accordance with the principles set out below.

1.7.4.1. General principles for the drafting of instructions

(a) The instructions must be drafted in one or more official Community languages. The words ‘Original instructions’ must appear on the language version(s) verified by the manufacturer or his authorised representative.

(b) Where no ‘Original instructions’ exist in the official language(s) of the country where the machinery is to be used, a translation into that/those language(s) must be provided by the manufacturer or his authorised representative or by the person bringing the machinery into the language area in question. The translations must bear the words ‘Translation of the original instructions’.

(c) The contents of the instructions must cover not only the intended use of the machinery but also take into account any reasonably foreseeable misuse thereof.

(d) In the case of machinery intended for use by non-professional operators, the wording and layout of the instructions for use must take into account the level of general education and acumen that can reasonably be expected from such operators.

1.7.4.2. Contents of the instructions

Each instruction manual must contain, where applicable, at least the following information:

(a) the business name and full address of the manufacturer and of his authorised representative;

(b) the designation of the machinery as marked on the machinery itself, except for the serial number (see section 1.7.3);

(c) the EC declaration of conformity, or a document setting out the contents of the EC declaration of conformity, showing the particulars of the machinery, not necessarily including the serial number and the signature;

(d) a general description of the machinery;

(e) the drawings, diagrams, descriptions and explanations necessary for the use, maintenance and repair of the machinery and for checking its correct functioning;

(f) a description of the workstation(s) likely to be occupied by operators;

(g) a description of the intended use of the machinery;

(h) warnings concerning ways in which the machinery must not be used that experience has shown might occur;

(i) assembly, installation and connection instructions, including drawings, diagrams and the means of attachment and the designation of the chassis or installation on which the machinery is to be mounted;

(j) instructions relating to installation and assembly for reducing noise or vibration;

(k) instructions for the putting into service and use of the machinery and, if necessary, instructions for the training of operators;

(l) information about the residual risks that remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted;

(m) instructions on the protective measures to be taken by the user, including, where appropriate, the personal protective equipment to be provided;

(n) the essential characteristics of tools which may be fitted to the machinery;

(o) the conditions in which the machinery meets the requirement of stability during use, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns;

(p) instructions with a view to ensuring that transport, handling and storage operations can be made safely, giving the mass of the machinery and of its various parts where these are regularly to be transported separately;

(q) the operating method to be followed in the event of accident or breakdown; if a blockage is likely to occur, the operating method to be followed so as to enable the equipment to be safely unblocked;
(v) the description of the adjustment and maintenance operations that should be carried out by the user and the preventive maintenance measures that should be observed;

(s) instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations;

(t) the specifications of the spare parts to be used, when these affect the health and safety of operators;

(u) the following information on airborne noise emissions:

— the A-weighted emission sound pressure level at workstations, where this exceeds 70 dB(A); where this level does not exceed 70 dB(A), this fact must be indicated,

— the peak C-weighted instantaneous sound pressure value at workstations, where this exceeds 63 Pa (130 dB in relation to 20 μPa),

— the A-weighted sound power level emitted by the machinery, where the A-weighted emission sound pressure level at workstations exceeds 80 dB(A).

These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced.

In the case of very large machinery, instead of the A-weighted sound power level, the A-weighted emission sound pressure levels at specified positions around the machinery may be indicated.

Where the harmonised standards are not applied, sound levels must be measured using the most appropriate method for the machinery. Whenever sound emission values are indicated the uncertainties surrounding these values must be specified. The operating conditions of the machinery during measurement and the measuring methods used must be described.

Where the workstation(s) are undefined or cannot be defined, A-weighted sound pressure levels must be measured at a distance of 1 metre from the surface of the machinery and at a height of 1.6 metres from the floor or access platform. The position and value of the maximum sound pressure must be indicated.

Where specific Community Directives lay down other requirements for the measurement of sound pressure levels or sound power levels, those Directives must be applied and the corresponding provisions of this section shall not apply;

(v) where machinery is likely to emit non-ionising radiation which may cause harm to persons, in particular persons with active or non-active implantable medical devices, information concerning the radiation emitted for the operator and exposed persons.

1.7.4.3. **Sales literature**

Sales literature describing the machinery must not contradict the instructions as regards health and safety aspects. Sales literature describing the performance characteristics of machinery must contain the same information on emissions as is contained in the instructions.

2. **SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR CERTAIN CATEGORIES OF MACHINERY**

Foodstuffs machinery, machinery for cosmetics or pharmaceutical products, hand-held and/or hand-guided machinery, portable fixing and other impact machinery, machinery for working wood and material with similar physical characteristics must meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).

2.1. **FOODSTUFFS MACHINERY AND MACHINERY FOR COSMETICS OR PHARMACEUTICAL PRODUCTS**

2.1.1. **General**

Machinery intended for use with foodstuffs or with cosmetics or pharmaceutical products must be designed and constructed in such a way as to avoid any risk of infection, sickness or contagion.
The following requirements must be observed:

(a) materials in contact with, or intended to come into contact with, foodstuffs or cosmetics or pharmaceutical products must satisfy the conditions set down in the relevant Directives. The machinery must be designed and constructed in such a way that these materials can be cleaned before each use. Where this is not possible disposable parts must be used;

(b) all surfaces in contact with foodstuffs or cosmetics or pharmaceutical products, other than surfaces of disposable parts, must:
   — be smooth and have neither ridges nor crevices which could harbour organic materials. The same applies to their joinings,
   — be designed and constructed in such a way as to reduce the projections, edges and recesses of assemblies to a minimum,
   — be easily cleaned and disinfected, where necessary after removing easily dismantled parts; the inside surfaces must have curves with a radius sufficient to allow thorough cleaning;

(c) it must be possible for liquids, gases and aerosols deriving from foodstuffs, cosmetics or pharmaceutical products as well as from cleaning, disinfecting and rinsing fluids to be completely discharged from the machinery (if possible, in a ‘cleaning’ position);

(d) machinery must be designed and constructed in such a way as to prevent any substances or living creatures, in particular insects, from entering, or any organic matter from accumulating in, areas that cannot be cleaned;

(e) machinery must be designed and constructed in such a way that no ancillary substances hazardous to health, including the lubricants used, can come into contact with foodstuffs, cosmetics or pharmaceutical products. Where necessary, machinery must be designed and constructed in such a way that continuing compliance with this requirement can be checked.

2.1.2. Instructions

The instructions for foodstuffs machinery and machinery for use with cosmetics or pharmaceutical products must indicate recommended products and methods for cleaning, disinfecting and rinsing, not only for easily accessible areas but also for areas to which access is impossible or inadvisable.

2.2. PORTABLE HAND-HELD AND/OR HAND-GUIDED MACHINERY

2.2.1. General

Portable hand-held and/or hand-guided machinery must:
   — depending on the type of machinery, have a supporting surface of sufficient size and have a sufficient number of handles and supports of an appropriate size, arranged in such a way as to ensure the stability of the machinery under the intended operating conditions,
   — except where technically impossible, or where there is an independent control device, in the case of handles which cannot be released in complete safety, be fitted with manual start and stop control devices arranged in such a way that the operator can operate them without releasing the handles,
   — present no risks of accidental starting and/or continued operation after the operator has released the handles. Equivalent steps must be taken if this requirement is not technically feasible,
   — permit, where necessary, visual observation of the danger zone and of the action of the tool with the material being processed.

The handles of portable machinery must be designed and constructed in such a way as to make starting and stopping straightforward.

2.2.1.1. Instructions

The instructions must give the following information concerning vibrations transmitted by portable hand-held and hand-guided machinery:
   — the vibration total value to which the hand-arm system is subjected, if it exceeds 2,5 m/s². Where this value does not exceed 2,5 m/s²; this must be mentioned,
   — the uncertainty of measurement.
These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced.

If harmonised standards are not applied, the vibration data must be measured using the most appropriate measurement code for the machinery.

The operating conditions during measurement and the methods used for measurement, or the reference of the harmonised standard applied, must be specified.

2.2.2. **Portable fixing and other impact machinery**

2.2.2.1. **General**

Portable fixing and other impact machinery must be designed and constructed in such a way that:

— energy is transmitted to the impacted element by the intermediary component that does not leave the device,

— an enabling device prevents impact unless the machinery is positioned correctly with adequate pressure on the base material,

— involuntary triggering is prevented; where necessary, an appropriate sequence of actions on the enabling device and the control device must be required to trigger an impact,

— accidental triggering is prevented during handling or in case of shock,

— loading and unloading operations can be carried out easily and safely.

Where necessary, it must be possible to fit the device with splinter guard(s) and the appropriate guard(s) must be provided by the manufacturer of the machinery.

2.2.2. **Instructions**

The instructions must give the necessary information regarding:

— the accessories and interchangeable equipment that can be used with the machinery,

— the suitable fixing or other impacted elements to be used with the machinery,

— where appropriate, the suitable cartridges to be used.

2.3. **MACHINERY FOR WORKING WOOD AND MATERIAL WITH SIMILAR PHYSICAL CHARACTERISTICS**

Machinery for working wood and materials with similar physical characteristics must comply with the following requirements:

(a) the machinery must be designed, constructed or equipped in such a way that the piece being machined can be placed and guided in safety; where the piece is hand-held on a work-bench, the latter must be sufficiently stable during the work and must not impede the movement of the piece;

(b) where the machinery is likely to be used in conditions involving the risk of ejection of workpieces or parts of them, it must be designed, constructed, or equipped in such a way as to prevent such ejection, or, if this is not possible, so that the ejection does not engender risks for the operator and/or exposed persons;

(c) the machinery must be equipped with an automatic brake that stops the tool in a sufficiently short time if there is a risk of contact with the tool whilst it runs down;

(d) where the tool is incorporated into a non-fully automated machine, the latter must be designed and constructed in such a way as to eliminate or reduce the risk of accidental injury.

3. **SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS DUE TO THE MOBILITY OF MACHINERY**

Machinery presenting hazards due to its mobility must meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).
3.1. GENERAL

3.1.1. Definitions

(a) ‘Machinery presenting hazards due to its mobility’ means
— machinery the operation of which requires either mobility while working, or continuous or semi-continuous movement between a succession of fixed working locations, or
— machinery which is operated without being moved, but which may be equipped in such a way as to enable it to be moved more easily from one place to another.

(b) ‘Driver’ means an operator responsible for the movement of a machine. The driver may be transported by the machinery or may be on foot, accompanying the machinery, or may guide the machinery by remote control.

3.2. WORK POSITIONS

3.2.1. Driving position

Visibility from the driving position must be such that the driver can, in complete safety for himself and the exposed persons, operate the machinery and its tools in their foreseeable conditions of use. Where necessary, appropriate devices must be provided to remedy hazards due to inadequate direct vision.

Machinery on which the driver is transported must be designed and constructed in such a way that, from the driving positions, there is no risk to the driver from inadvertent contact with the wheels and tracks.

The driving position of ride-on drivers must be designed and constructed in such a way that a driver’s cab may be fitted, provided this does not increase the risk and there is room for it. The cab must incorporate a place for the instructions needed for the driver.

3.2.2. Seating

Where there is a risk that operators or other persons transported by the machinery may be crushed between parts of the machinery and the ground should the machinery roll or tip over, in particular for machinery equipped with a protective structure referred to in section 3.4.3 or 3.4.4, their seats must be designed or equipped with a restraint system so as to keep the persons in their seats, without restricting movements necessary for operations or movements relative to the structure caused by the suspension of the seats. Such restraint systems should not be fitted if they increase the risk.

3.2.3. Positions for other persons

If the conditions of use provide that persons other than the driver may occasionally or regularly be transported by the machinery or work on it, appropriate positions must be provided which enable them to be transported or to work on it without risk.

The second and third paragraphs of section 3.2.1 also apply to the places provided for persons other than the driver.

3.3. CONTROL SYSTEMS

If necessary, steps must be taken to prevent unauthorised use of controls.

In the case of remote controls, each control unit must clearly identify the machinery to be controlled from that unit.

The remote control system must be designed and constructed in such a way as to affect only:
— the machinery in question,
— the functions in question.

Remote controlled machinery must be designed and constructed in such a way that it will respond only to signals from the intended control units.
3.3.1. **Control devices**

The driver must be able to actuate all control devices required to operate the machinery from the driving position, except for functions which can be safely actuated only by using control devices located elsewhere. These functions include, in particular, those for which operators other than the driver are responsible or for which the driver has to leave the driving position in order to control them safely.

Where there are pedals, they must be so designed, constructed and fitted as to allow safe operation by the driver with the minimum risk of incorrect operation. They must have a slip-resistant surface and be easy to clean.

Where their operation can lead to hazards, notably dangerous movements, the control devices, except for those with preset positions, must return to the neutral position as soon as they are released by the operator.

In the case of wheeled machinery, the steering system must be designed and constructed in such a way as to reduce the force of sudden movements of the steering wheel or the steering lever caused by shocks to the guide wheels.

Any control that locks the differential must be so designed and arranged that it allows the differential to be unlocked when the machinery is moving.

The sixth paragraph of section 1.2.2, concerning acoustic and/or visual warning signals, applies only in the case of reversing.

3.3.2. **Starting/moving**

All travel movements of self-propelled machinery with a ride-on driver must be possible only if the driver is at the controls.

Where, for operating purposes, machinery is fitted with devices which exceed its normal clearance zone (e.g. stabilisers, jib, etc.), the driver must be provided with the means of checking easily, before moving the machinery, that such devices are in a particular position which allows safe movement.

This also applies to all other parts which, to allow safe movement, have to be in particular positions, locked if necessary.

Where it does not give rise to other risks, movement of the machinery must depend on safe positioning of the aforementioned parts.

It must not be possible for unintentional movement of the machinery to occur while the engine is being started.

3.3.3. **Travelling function**

Without prejudice to road traffic regulations, self-propelled machinery and its trailers must meet the requirements for slowing down, stopping, braking and immobilisation so as to ensure safety under all the operating, load, speed, ground and gradient conditions allowed for.

The driver must be able to slow down and stop self-propelled machinery by means of a main device. Where safety so requires, in the event of a failure of the main device, or in the absence of the energy supply needed to actuate the main device, an emergency device with a fully independent and easily accessible control device must be provided for slowing down and stopping.

Where safety so requires, a parking device must be provided to render stationary machinery immobile. This device may be combined with one of the devices referred to in the second paragraph, provided that it is purely mechanical.

Remote-controlled machinery must be equipped with devices for stopping operation automatically and immediately and for preventing potentially dangerous operation in the following situations:

— if the driver loses control,
— if it receives a stop signal,
— if a fault is detected in a safety-related part of the system,
— if no validation signal is detected within a specified time.

Section 1.2.4 does not apply to the travelling function.
3.3.4. **Movement of pedestrian-controlled machinery**

Movement of pedestrian-controlled self-propelled machinery must be possible only through sustained action on the relevant control device by the driver. In particular, it must not be possible for movement to occur while the engine is being started.

The control systems for pedestrian-controlled machinery must be designed in such a way as to minimise the risks arising from inadvertent movement of the machine towards the driver, in particular:

— crushing,
— injury from rotating tools.

The speed of travel of the machinery must be compatible with the pace of a driver on foot.

In the case of machinery on which a rotary tool may be fitted, it must not be possible to actuate the tool when the reverse control is engaged, except where the movement of the machinery results from movement of the tool. In the latter case, the reversing speed must be such that it does not endanger the driver.

3.3.5. **Control circuit failure**

A failure in the power supply to the power-assisted steering, where fitted, must not prevent machinery from being steered during the time required to stop it.

3.4. **PROTECTION AGAINST MECHANICAL HAZARDS**

3.4.1. **Uncontrolled movements**

Machinery must be designed, constructed and where appropriate placed on its mobile support in such a way as to ensure that, when moved, uncontrolled oscillations of its centre of gravity do not affect its stability or exert excessive strain on its structure.

3.4.2. **Moving transmission parts**

By way of exception to section 1.3.8.1, in the case of engines, moveable guards preventing access to the moving parts in the engine compartment need not have interlocking devices if they have to be opened either by the use of a tool or key or by a control located in the driving position, providing the latter is in a fully enclosed cab with a lock to prevent unauthorised access.

3.4.3. **Roll-over and tip-over**

Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk of rolling or tipping over, the machinery must be fitted with an appropriate protective structure, unless this increases the risk.

This structure must be such that in the event of rolling or tipping over it affords the ride-on person(s) an adequate deflection-limiting volume.

In order to verify that the structure complies with the requirement laid down in the second paragraph, the manufacturer or his authorised representative must, for each type of structure concerned, perform appropriate tests or have such tests performed.

3.4.4. **Falling objects**

Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk due to falling objects or material, the machinery must be designed and constructed in such a way as to take account of this risk and fitted, if its size allows, with an appropriate protective structure.

This structure must be such that, in the event of falling objects or material, it guarantees the ride-on person(s) an adequate deflection-limiting volume.

In order to verify that the structure complies with the requirement laid down in the second paragraph, the manufacturer or his authorised representative must, for each type of structure concerned, perform appropriate tests or have such tests performed.

3.4.5. **Means of access**

Handholds and steps must be designed, constructed and arranged in such a way that the operators use them instinctively and do not use the control devices to assist access.
3.4.6. **Towing devices**

All machinery used to tow or to be towed must be fitted with towing or coupling devices designed, constructed and arranged in such a way as to ensure easy and secure connection and disconnection and to prevent accidental disconnection during use.

Insofar as the tow bar load so requires, such machinery must be equipped with a support with a bearing surface suited to the load and the ground.

3.4.7. **Transmission of power between self-propelled machinery (or tractor) and recipient machinery**

Removable mechanical transmission devices linking self-propelled machinery (or a tractor) to the first fixed bearing of recipient machinery must be designed and constructed in such a way that any part that moves during operation is protected over its whole length.

On the side of the self-propelled machinery (or tractor), the power take-off to which the removable mechanical transmission device is attached must be protected either by a guard fixed and linked to the self-propelled machinery (or tractor) or by any other device offering equivalent protection.

It must be possible to open this guard for access to the removable transmission device. Once it is in place, there must be enough room to prevent the drive shaft damaging the guard when the machinery (or the tractor) is moving.

On the recipient machinery side, the input shaft must be enclosed in a protective casing fixed to the machinery.

Torque limiters or freewheels may be fitted to universal joint transmissions only on the side adjoining the driven machinery. The removable mechanical transmission device must be marked accordingly.

All recipient machinery, the operation of which requires a removable mechanical transmission device to connect it to self-propelled machinery (or a tractor), must have a system for attaching the removable mechanical transmission device so that, when the machinery is uncoupled, the removable mechanical transmission device and its guard are not damaged by contact with the ground or part of the machinery.

The outside parts of the guard must be so designed, constructed and arranged that they cannot turn with the removable mechanical transmission device. The guard must cover the transmission to the ends of the inner jaws in the case of simple universal joints and at least to the centre of the outer joint or joints in the case of wide-angle universal joints.

If means of access to working positions are provided near to the removable mechanical transmission device, they must be designed and constructed in such a way that the shaft guards cannot be used as steps, unless designed and constructed for that purpose.

3.5. **PROTECTION AGAINST OTHER HAZARDS**

3.5.1. **Batteries**

The battery housing must be designed and constructed in such a way as to prevent the electrolyte being ejected on to the operator in the event of rollover or tipover and to avoid the accumulation of vapours in places occupied by operators.

Machinery must be designed and constructed in such a way that the battery can be disconnected with the aid of an easily accessible device provided for that purpose.

3.5.2. **Fire**

Depending on the hazards anticipated by the manufacturer, machinery must, where its size permits:

— either allow easily accessible fire extinguishers to be fitted, or

— be provided with built-in extinguisher systems.

3.5.3. **Emissions of hazardous substances**

The second and third paragraphs of section 1.5.13 do not apply where the main function of the machinery is the spraying of products. However, the operator must be protected against the risk of exposure to such hazardous emissions.
3.6. INFORMATION AND INDICATIONS

3.6.1. Signs, signals and warnings

All machinery must have signs and/or instruction plates concerning use, adjustment and maintenance, wherever necessary, so as to ensure the health and safety of persons. They must be chosen, designed and constructed in such a way as to be clearly visible and indelible.

Without prejudice to the provisions of road traffic regulations, machinery with a ride-on driver must have the following equipment:

— an acoustic warning device to alert persons,

— a system of light signals relevant to the intended conditions of use; the latter requirement does not apply to machinery intended solely for underground working and having no electrical power,

— where necessary, there must be an appropriate connection between a trailer and the machinery for the operation of signals.

Remote-controlled machinery which, under normal conditions of use, exposes persons to the risk of impact or crushing must be fitted with appropriate means to signal its movements or with means to protect persons against such risks. The same applies to machinery which involves, when in use, the constant repetition of a forward and backward movement on a single axis where the area to the rear of the machine is not directly visible to the driver.

Machinery must be constructed in such a way that the warning and signalling devices cannot be disabled unintentionally. Where it is essential for safety, such devices must be provided with the means to check that they are in good working order and their failure must be made apparent to the operator.

Where the movement of machinery or its tools is particularly hazardous, signs on the machinery must be provided to warn against approaching the machinery while it is working; the signs must be legible at a sufficient distance to ensure the safety of persons who have to be in the vicinity.

3.6.2. Marking

The following must be shown legibly and indelibly on all machinery:

— nominal power expressed in kilowatts (kW),

— mass of the most usual configuration, in kilograms (kg);

and, where appropriate:

— maximum drawbar pull provided for at the coupling hook, in Newtons (N),

— maximum vertical load provided for on the coupling hook, in Newtons (N).

3.6.3. Instructions

3.6.3.1. Vibrations

The instructions must give the following information concerning vibrations transmitted by the machinery to the hand-arm system or to the whole body:

— the vibration total value to which the hand-arm system is subjected, if it exceeds 2,5 m/s². Where this value does not exceed 2,5 m/s², this must be mentioned,

— the highest root mean square value of weighted acceleration to which the whole body is subjected, if it exceeds 0,5 m/s². Where this value does not exceed 0,5 m/s², this must be mentioned,

— the uncertainty of measurement.

These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced.
Where harmonised standards are not applied, the vibration must be measured using the most appropriate measurement code for the machinery concerned.

The operating conditions during measurement and the measurement codes used must be described.

3.6.3.2. Multiple uses

The instructions for machinery allowing several uses depending on the equipment used and the instructions for the interchangeable equipment must contain the information necessary for safe assembly and use of the basic machinery and the interchangeable equipment that can be fitted.

4. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS DUE TO LIFTING OPERATIONS

Machinery presenting hazards due to lifting operations must meet all the relevant essential health and safety requirements described in this chapter (see General Principles, point 4).

4.1. GENERAL

4.1.1. Definitions

(a) ‘Lifting operation’ means a movement of unit loads consisting of goods and/or persons necessitating, at a given moment, a change of level.

(b) ‘Guided load’ means a load where the total movement is made along rigid or flexible guides whose position is determined by fixed points.

(c) ‘Working coefficient’ means the arithmetic ratio between the load guaranteed by the manufacturer or his authorised representative up to which a component is able to hold it and the maximum working load marked on the component.

(d) ‘Test coefficient’ means the arithmetic ratio between the load used to carry out the static or dynamic tests on lifting machinery or a lifting accessory and the maximum working load marked on the lifting machinery or lifting accessory.

(e) ‘Static test’ means the test during which lifting machinery or a lifting accessory is first inspected and subjected to a force corresponding to the maximum working load multiplied by the appropriate static test coefficient and then re-inspected once the said load has been released to ensure that no damage has occurred.

(f) ‘Dynamic test’ means the test during which lifting machinery is operated in all its possible configurations at the maximum working load multiplied by the appropriate dynamic test coefficient with account being taken of the dynamic behaviour of the lifting machinery in order to check that it functions properly.

(g) ‘Carrier’ means a part of the machinery on or in which persons and/or goods are supported in order to be lifted.

4.1.2. Protection against mechanical hazards

4.1.2.1. Risks due to lack of stability

Machinery must be designed and constructed in such a way that the stability required by section 1.3.1 is maintained both in service and out of service, including all stages of transportation, assembly and dismantling, during foreseeable component failures and also during the tests carried out in accordance with the instruction handbook. To that end, the manufacturer or his authorised representative must use the appropriate verification methods.

4.1.2.2. Machinery running on guide rails and rail tracks

Machinery must be provided with devices which act on the guide rails or tracks to prevent derailment.

If, despite such devices, there remains a risk of derailment or of failure of a rail or of a running component, devices must be provided which prevent the equipment, component or load from falling or the machinery from overturning.
4.1.2.3. **Mechanical strength**

Machinery, lifting accessories and their components must be capable of withstanding the stresses to which they are subjected, both in and, where applicable, out of use, under the installation and operating conditions provided for and in all relevant configurations, with due regard, where appropriate, to the effects of atmospheric factors and forces exerted by persons. This requirement must also be satisfied during transport, assembly and dismantling.

Machinery and lifting accessories must be designed and constructed in such a way as to prevent failure from fatigue and wear, taking due account of their intended use.

The materials used must be chosen on the basis of the intended working environments, with particular regard to corrosion, abrasion, impacts, extreme temperatures, fatigue, brittleness and ageing.

Machinery and lifting accessories must be designed and constructed in such a way as to withstand the overload in the static tests without permanent deformation or patent defect. Strength calculations must take account of the value of the static test coefficient chosen to guarantee an adequate level of safety. That coefficient has, as a general rule, the following values:

(a) manually-operated machinery and lifting accessories: 1.5;
(b) other machinery: 1.25.

Machinery must be designed and constructed in such a way as to undergo, without failure, the dynamic tests carried out using the maximum working load multiplied by the dynamic test coefficient. This dynamic test coefficient is chosen so as to guarantee an adequate level of safety; the coefficient is, as a general rule, equal to 1.1. As a general rule, the tests will be performed at the nominal speeds provided for. Should the control circuit of the machinery allow for a number of simultaneous movements, the tests must be carried out under the least favourable conditions, as a general rule by combining the movements concerned.

### 4.1.2.4. **Pulleys, drums, wheels, ropes and chains**

Pulleys, drums and wheels must have a diameter commensurate with the size of the ropes or chains with which they can be fitted.

Drums and wheels must be designed, constructed and installed in such a way that the ropes or chains with which they are equipped can be wound without coming off.

Ropes used directly for lifting or supporting the load must not include any splicing other than at their ends. Splicings are, however, tolerated in installations which are intended by design to be modified regularly according to needs of use.

Complete ropes and their endings must have a working coefficient chosen in such a way as to guarantee an adequate level of safety. As a general rule, this coefficient is equal to 5.

Lifting chains must have a working coefficient chosen in such a way as to guarantee an adequate level of safety. As a general rule, this coefficient is equal to 4.

In order to verify that an adequate working coefficient has been attained, the manufacturer or his authorised representative must, for each type of chain and rope used directly for lifting the load and for the rope ends, perform the appropriate tests or have such tests performed.

### 4.1.2.5. **Lifting accessories and their components**

Lifting accessories and their components must be sized with due regard to fatigue and ageing processes for a number of operating cycles consistent with their expected life-span as specified in the operating conditions for a given application.

Moreover:

(a) the working coefficient of wire-rope/rope-end combinations must be chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 5. Ropes must not comprise any splices or loops other than at their ends;

(b) where chains with welded links are used, they must be of the short-link type. The working coefficient of chains must be chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 4;
(c) the working coefficient for textile ropes or slings is dependent on the material, method of manufacture, dimensions and use. This coefficient must be chosen in such a way as to guarantee an adequate level of safety; it is, as a general rule, equal to 7, provided the materials used are shown to be of very good quality and the method of manufacture is appropriate to the intended use. Should this not be the case, the coefficient is, as a general rule, set at a higher level in order to secure an equivalent level of safety. Textile ropes and slings must not include any knots, connections or splicing other than at the ends of the sling, except in the case of an endless sling;

(d) all metallic components making up, or used with, a sling must have a working coefficient chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 4;

(e) the maximum working load of a multilegged sling is determined on the basis of the working coefficient of the weakest leg, the number of legs and a reduction factor which depends on the slinging configuration;

(f) in order to verify that an adequate working coefficient has been attained, the manufacturer or his authorised representative must, for each type of component referred to in (a), (b), (c) and (d), perform the appropriate tests or have such tests performed.

4.1.2.6. Control of movements

Devices for controlling movements must act in such a way that the machinery on which they are installed is kept safe.

(a) Machinery must be designed and constructed or fitted with devices in such a way that the amplitude of movement of its components is kept within the specified limits. The operation of such devices must, where appropriate, be preceded by a warning.

(b) Where several fixed or rail-mounted machines can be manoeuvred simultaneously in the same place, with risks of collision, such machinery must be designed and constructed in such a way as to make it possible to fit systems enabling these risks to be avoided.

(c) Machinery must be designed and constructed in such a way that the loads cannot creep dangerously or fall freely and unexpectedly, even in the event of partial or total failure of the power supply or when the operator stops operating the machine.

(d) It must not be possible, under normal operating conditions, to lower the load solely by friction brake, except in the case of machinery whose function requires it to operate in that way.

(e) Holding devices must be designed and constructed in such a way that inadvertent dropping of the loads is avoided.

4.1.2.7. Movements of loads during handling

The operating position of machinery must be located in such a way as to ensure the widest possible view of trajectories of the moving parts, in order to avoid possible collisions with persons, equipment or other machinery which might be manoeuvring at the same time and liable to constitute a hazard.

Machinery with guided loads must be designed and constructed in such a way as to prevent persons from being injured by movement of the load, the carrier or the counterweights, if any.

4.1.2.8. Machinery serving fixed landings

4.1.2.8.1. Movements of the carrier

The movement of the carrier of machinery serving fixed landings must be rigidly guided to and at the landings. Scissor systems are also regarded as rigid guidance.

4.1.2.8.2. Access to the carrier

Where persons have access to the carrier, the machinery must be designed and constructed in such a way as to ensure that the carrier remains stationary during access, in particular while it is being loaded or unloaded.

The machinery must be designed and constructed in such a way as to ensure that the difference in level between the carrier and the landing being served does not create a risk of tripping.
4.1.2.8.3. Risks due to contact with the moving carrier

Where necessary in order to fulfil the requirement expressed in the second paragraph of section 4.1.2.7, the travel zone must be rendered inaccessible during normal operation.

When, during inspection or maintenance, there is a risk that persons situated under or above the carrier may be crushed between the carrier and any fixed parts, sufficient free space must be provided either by means of physical refuges or by means of mechanical devices blocking the movement of the carrier.

4.1.2.8.4. Risk due to the load falling off the carrier

Where there is a risk due to the load falling off the carrier, the machinery must be designed and constructed in such a way as to prevent this risk.

4.1.2.8.5. Landings

Risks due to contact of persons at landings with the moving carrier or other moving parts must be prevented.

Where there is a risk due to persons falling into the travel zone when the carrier is not present at the landings, guards must be fitted in order to prevent this risk. Such guards must not open in the direction of the travel zone. They must be fitted with an interlocking device controlled by the position of the carrier that prevents:

— hazardous movements of the carrier until the guards are closed and locked,
— hazardous opening of a guard until the carrier has stopped at the corresponding landing.

4.1.3. Fitness for purpose

When lifting machinery or lifting accessories are placed on the market or are first put into service, the manufacturer or his authorised representative must ensure, by taking appropriate measures or having them taken, that the machinery or the lifting accessories which are ready for use — whether manually or power-operated — can fulfil their specified functions safely.

The static and dynamic tests referred to in section 4.1.2.3 must be performed on all lifting machinery ready to be put into service.

Where the machinery cannot be assembled in the manufacturer's premises or in the premises of his authorised representative, the appropriate measures must be taken at the place of use. Otherwise, the measures may be taken either in the manufacturer's premises or at the place of use.

4.2. REQUIREMENTS FOR MACHINERY WHOSE POWER SOURCE IS OTHER THAN MANUAL EFFORT

4.2.1. Control of movements

Hold-to-run control devices must be used to control the movements of the machinery or its equipment. However, for partial or complete movements in which there is no risk of the load or the machinery colliding, the said devices may be replaced by control devices authorising automatic stops at pre-selected positions without the operator holding a hold-to-run control device.

4.2.2. Loading control

Machinery with a maximum working load of not less than 1 000 kilograms or an overturning moment of not less than 40 000 Nm must be fitted with devices to warn the driver and prevent dangerous movements in the event:

— of overloading, either as a result of the maximum working load or the maximum working moment due to the load being exceeded, or
— of the overturning moment being exceeded.

4.2.3. Installations guided by ropes

Rope carriers, tractors or tractor carriers must be held by counterweights or by a device allowing permanent control of the tension.
4.3. INFORMATION AND MARKINGS

4.3.1. Chains, ropes and webbing

Each length of lifting chain, rope or webbing not forming part of an assembly must bear a mark or, where this is not possible, a plate or irremovable ring bearing the name and address of the manufacturer or his authorised representative and the identifying reference of the relevant certificate.

The certificate mentioned above must show at least the following information:

(a) the name and address of the manufacturer and, if appropriate, his authorised representative;

(b) a description of the chain or rope which includes:
   — its nominal size,
   — its construction,
   — the material from which it is made, and
   — any special metallurgical treatment applied to the material;

(c) the test method used;

(d) the maximum load to which the chain or rope should be subjected in service. A range of values may be given on the basis of the intended applications.

4.3.2. Lifting accessories

Lifting accessories must show the following particulars:

— identification of the material where this information is needed for safe use,

— the maximum working load.

In the case of lifting accessories on which marking is physically impossible, the particulars referred to in the first paragraph must be displayed on a plate or other equivalent means and securely affixed to the accessory.

The particulars must be legible and located in a place where they are not liable to disappear as a result of wear or jeopardise the strength of the accessory.

4.3.3. Lifting machinery

The maximum working load must be prominently marked on the machinery. This marking must be legible, indelible and in an un-coded form.

Where the maximum working load depends on the configuration of the machinery, each operating position must be provided with a load plate indicating, preferably in diagrammatic form or by means of tables, the working load permitted for each configuration.

Machinery intended for lifting goods only, equipped with a carrier which allows access to persons, must bear a clear and indelible warning prohibiting the lifting of persons. This warning must be visible at each place where access is possible.

4.4. INSTRUCTIONS

4.4.1. Lifting accessories

Each lifting accessory or each commercially indivisible batch of lifting accessories must be accompanied by instructions setting out at least the following particulars:

(a) the intended use;

(b) the limits of use (particularly for lifting accessories such as magnetic or vacuum pads which do not fully comply with section 4.1.2.6(e));

(c) instructions for assembly, use and maintenance;

(d) the static test coefficient used.
4.4.2. Lifting machinery

Lifting machinery must be accompanied by instructions containing information on:

(a) the technical characteristics of the machinery, and in particular:
   — the maximum working load and, where appropriate, a copy of the load plate or load table described in the second paragraph of section 4.3.3.
   — the reactions at the supports or anchors and, where appropriate, characteristics of the tracks,
   — where appropriate, the definition and the means of installation of the ballast;

(b) the contents of the logbook, if the latter is not supplied with the machinery;

(c) advice for use, particularly to offset the lack of direct vision of the load by the operator;

(d) where appropriate, a test report detailing the static and dynamic tests carried out by or for the manufacturer or his authorised representative;

(e) for machinery which is not assembled on the premises of the manufacturer in the form in which it is to be used, the necessary instructions for performing the measures referred to in section 4.1.3 before it is first put into service.

5. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY INTENDED FOR UNDERGROUND WORK

Machinery intended for underground work must meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).

5.1. RISKS DUE TO LACK OF STABILITY

Powered roof supports must be designed and constructed in such a way as to maintain a given direction when moving and not slip before and while they come under load and after the load has been removed. They must be equipped with anchorages for the top plates of the individual hydraulic props.

5.2. MOVEMENT

Powered roof supports must allow for unhindered movement of persons.

5.3. CONTROL DEVICES

The accelerator and brake controls for movement of machinery running on rails must be hand-operated. However, enabling devices may be foot-operated.

The control devices of powered roof supports must be designed and positioned in such a way that, during displacement operations, operators are sheltered by a support in place. The control devices must be protected against any accidental release.

5.4. STOPPING

Self-propelled machinery running on rails for use in underground work must be equipped with an enabling device acting on the circuit controlling the movement of the machinery such that movement is stopped if the driver is no longer in control of the movement.

5.5. FIRE

The second indent of section 3.5.2 is mandatory in respect of machinery which comprises highly flammable parts.

The braking system of machinery intended for use in underground workings must be designed and constructed in such a way that it does not produce sparks or cause fires.

Machinery with internal combustion engines for use in underground workings must be fitted only with engines using fuel with a low vaporising pressure and which exclude any spark of electrical origin.
5.6. EXHAUST EMISSIONS

Exhaust emissions from internal combustion engines must not be discharged upwards.

6. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY PRESENTING PARTICULAR HAZARDS DUE TO THE LIFTING OF PERSONS

Machinery presenting hazards due to the lifting of persons must meet all the relevant essential health and safety requirements described in this chapter (see General Principles, point 4).

6.1. GENERAL

6.1.1. Mechanical strength

The carrier, including any trapdoors, must be designed and constructed in such a way as to offer the space and strength corresponding to the maximum number of persons permitted on the carrier and the maximum working load.

The working coefficients for components set out in sections 4.1.2.4 and 4.1.2.5 are inadequate for machinery intended for the lifting of persons and must, as a general rule, be doubled. Machinery intended for lifting persons or persons and goods must be fitted with a suspension or supporting system for the carrier designed and constructed in such a way as to ensure an adequate overall level of safety and to prevent the risk of the carrier falling.

If ropes or chains are used to suspend the carrier, as a general rule, at least two independent ropes or chains are required, each with its own anchorage.

6.1.2. Loading control for machinery moved by power other than human strength

The requirements of section 4.2.2 apply regardless of the maximum working load and overturning moment, unless the manufacturer can demonstrate that there is no risk of overloading or overturning.

6.2. CONTROL DEVICES

Where safety requirements do not impose other solutions, the carrier must, as a general rule, be designed and constructed in such a way that persons in the carrier have means of controlling upward and downward movements and, if appropriate, other movements of the carrier.

In operation, those control devices must override any other devices controlling the same movement with the exception of emergency stop devices.

The control devices for these movements must be of the hold-to-run type except where the carrier itself is completely enclosed.

6.3. RISKS TO PERSONS IN OR ON THE CARRIER

6.3.1. Risks due to movements of the carrier

Machinery for lifting persons must be designed, constructed or equipped in such a way that the acceleration or deceleration of the carrier does not engender risks for persons.

6.3.2. Risk of persons falling from the carrier

The carrier must not tilt to an extent which creates a risk of the occupants falling, including when the machinery and carrier are moving.

Where the carrier is designed as a work station, provision must be made to ensure stability and to prevent hazardous movements.
If the measures referred to in section 1.5.15 are not adequate, carriers must be fitted with a sufficient number of suitable anchorage points for the number of persons permitted on the carrier. The anchorage points must be strong enough for the use of personal protective equipment against falls from a height. Any trapdoor in floors or ceilings or side doors must be designed and constructed in such a way as to prevent inadvertent opening and must open in a direction that obviates any risk of falling, should they open unexpectedly.

6.3.3. **Risk due to objects falling on the carrier**

Where there is a risk of objects falling on the carrier and endangering persons, the carrier must be equipped with a protective roof.

6.4. **MACHINERY SERVING FIXED LANDINGS**

6.4.1. **Risks to persons in or on the carrier**

The carrier must be designed and constructed in such a way as to prevent risks due to contact between persons and/or objects in or on the carrier with any fixed or moving elements. Where necessary in order to fulfil this requirement, the carrier itself must be completely enclosed with doors fitted with an interlocking device that prevents hazardous movements of the carrier unless the doors are closed. The doors must remain closed if the carrier stops between landings where there is a risk of falling from the carrier.

The machinery must be designed, constructed and, where necessary, equipped with devices in such a way as to prevent uncontrolled upward or downward movement of the carrier. These devices must be able to stop the carrier at its maximum working load and at the foreseeable maximum speed. The stopping action must not cause deceleration harmful to the occupants, whatever the load conditions.

6.4.2. **Controls at landings**

Controls, other than those for emergency use, at landings must not initiate movements of the carrier when:
— the control device in the carrier is being operated,
— the carrier is not at a landing.

6.4.3. **Access to the carrier**

The guards at the landings and on the carrier must be designed and constructed in such a way as to ensure safe transfer to and from the carrier, taking into consideration the foreseeable range of goods and persons to be lifted.

6.5. **MARKINGS**

The carrier must bear the information necessary to ensure safety including:
— the number of persons permitted on the carrier,
— the maximum working load.
ANNEX II

Declarations

1. CONTENT

A. EC DECLARATION OF CONFORMITY OF THE MACHINERY

This declaration and translations thereof must be drawn up under the same conditions as the instructions (see Annex I, section 1.7.4.1(a) and (b)), and must be typewritten or else handwritten in capital letters.

This declaration relates exclusively to the machinery in the state in which it was placed on the market, and excludes components which are added and/or operations carried out subsequently by the final user.

The EC declaration of conformity must contain the following particulars:

1. business name and full address of the manufacturer and, where appropriate, his authorised representative;
2. name and address of the person authorised to compile the technical file, who must be established in the Community;
3. description and identification of the machinery, including generic denomination, function, model, type, serial number and commercial name;
4. a sentence expressly declaring that the machinery fulfils all the relevant provisions of this Directive and where appropriate, a similar sentence declaring the conformity with other Directives and/or relevant provisions with which the machinery complies. These references must be those of the texts published in the Official Journal of the European Union;
5. where appropriate, the name, address and identification number of the notified body which carried out the EC type-examination referred to in Annex IX and the number of the EC type-examination certificate;
6. where appropriate, the name, address and identification number of the notified body which approved the full quality assurance system referred to in Annex X;
7. where appropriate, a reference to the harmonised standards used, as referred to in Article 7(2);
8. where appropriate, the reference to other technical standards and specifications used;
9. the place and date of the declaration;
10. the identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorised representative.

B. DECLARATION OF INCORPORATION OF PARTLY COMPLETED MACHINERY

This declaration and translations thereof must be drawn up under the same conditions as the instructions (see Annex I, section 1.7.4.1(a) and (b)), and must be typewritten or else handwritten in capital letters.

The declaration of incorporation must contain the following particulars:

1. business name and full address of the manufacturer of the partly completed machinery and, where appropriate, his authorised representative;
2. name and address of the person authorised to compile the relevant technical documentation, who must be established in the Community;
3. description and identification of the partly completed machinery including generic denomination, function, model, type, serial number and commercial name;
4. a sentence declaring which essential requirements of this Directive are applied and fulfilled and that the relevant technical documentation is compiled in accordance with part B of Annex VII, and, where appropriate, a sentence declaring the conformity of the partly completed machinery with other relevant Directives. These references must be those of the texts published in the Official Journal of the European Union;
5. an undertaking to transmit, in response to a reasoned request by the national authorities, relevant information on the partly completed machinery. This shall include the method of transmission and shall be without prejudice to the intellectual property rights of the manufacturer of the partly completed machinery;
6. a statement that the partly completed machinery must not be put into service until the final machinery into which it is to be incorporated has been declared in conformity with the provisions of this Directive, where appropriate;
7. the place and date of the declaration;
8. the identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorised representative.
2. CUSTODY

The manufacturer of machinery or his authorised representative shall keep the original EC declaration of conformity for a period of at least 10 years from the last date of manufacture of the machinery.

The manufacturer of partly completed machinery or his authorised representative shall keep the original declaration of incorporation for a period of at least 10 years from the last date of manufacture of the partly completed machinery.
ANNEX III

CE marking

The CE conformity marking shall consist of the initials 'CE' taking the following form:

If the CE marking is reduced or enlarged the proportions shown in the above drawing must be respected.

The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm. The minimum dimension may be waived for small-scale machinery.

The CE marking must be affixed in the immediate vicinity of the name of the manufacturer or his authorised representative, using the same technique.

Where the full quality assurance procedure referred to in Article 12(3)(c) and 12(4)(b) has been applied, the CE marking must be followed by the identification number of the notified body.
ANNEX IV

Categories of machinery to which one of the procedures referred to in Article 12(3) and (4) must be applied

1. Circular saws (single- or multi-blade) for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:
   1.1. sawing machinery with fixed blade(s) during cutting, having a fixed bed or support with manual feed of the workpiece or with a demountable power feed;
   1.2. sawing machinery with fixed blade(s) during cutting, having a manually operated reciprocating saw-bench or carriage;
   1.3. sawing machinery with fixed blade(s) during cutting, having a built-in mechanical feed device for the workpieces, with manual loading and/or unloading;
   1.4. sawing machinery with movable blade(s) during cutting, having mechanical movement of the blade, with manual loading and/or unloading.
3. Thicknessers for one-side dressing having a built-in mechanical feed device, with manual loading and/or unloading for woodworking.
4. Band-saws with manual loading and/or unloading for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:
   4.1. sawing machinery with fixed blade(s) during cutting, having a fixed or reciprocating-movement bed or support for the workpiece;
   4.2. sawing machinery with blade(s) assembled on a carriage with reciprocating motion.
5. Combined machinery of the types referred to in points 1 to 4 and in point 7 for working with wood and material with similar physical characteristics.
6. Hand-fed tenoning machinery with several tool holders for woodworking.
7. Hand-fed vertical spindle moulding machinery for working with wood and material with similar physical characteristics.
8. Portable chainsaws for woodworking.
9. Presses, including press-brakes, for the cold working of metals, with manual loading and/or unloading, whose movable working parts may have a travel exceeding 6 mm and a speed exceeding 30 mm/s.
10. Injection or compression plastics-moulding machinery with manual loading or unloading.
11. Injection or compression rubber-moulding machinery with manual loading or unloading.
12. Machinery for underground working of the following types:
   12.1. locomotives and brake-vans;
   12.2. hydraulic-powered roof supports.
13. Manually loaded trucks for the collection of household refuse incorporating a compression mechanism.
14. Removable mechanical transmission devices including their guards.
15. Guards for removable mechanical transmission devices.
17. Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than three metres.
18. Portable cartridge-operated fixing and other impact machinery.
19. Protective devices designed to detect the presence of persons.
20. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9, 10 and 11.
21. Logic units to ensure safety functions.
22. Roll-over protective structures (ROPS).
23. Falling-object protective structures (FOPS).
ANNEX V

Indicative list of the safety components referred to in Article 2(c)

1. Guards for removable mechanical transmission devices.
2. Protective devices designed to detect the presence of persons.
3. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in items 9, 10 and 11 of Annex IV.
4. Logic units to ensure safety functions.
5. Valves with additional means for failure detection intended for the control of dangerous movements on machinery.
7. Guards and protective devices designed to protect persons against moving parts involved in the process on the machinery.
8. Monitoring devices for loading and movement control in lifting machinery.
9. Restraint systems to keep persons on their seats.
11. Discharging systems to prevent the build-up of potentially dangerous electrostatic charges.
12. Energy limiters and relief devices referred to in sections 1.5.7, 3.4.7 and 4.1.2.6 of Annex I.
13. Systems and devices to reduce the emission of noise and vibrations.
14. Roll-over protective structures (ROPS).
15. Falling-object protective structures (FOPS).
16. Two-hand control devices.
17. Components for machinery designed for lifting and/or lowering persons between different landings and included in the following list:
   (a) devices for locking landing doors;
   (b) devices to prevent the load-carrying unit from falling or unchecked upwards movement;
   (c) overspeed limitation devices;
   (d) energy-accumulating shock absorbers,
       — non-linear, or
       — with damping of the return movement;
   (e) energy-dissipating shock absorbers;
   (f) safety devices fitted to jacks of hydraulic power circuits where these are used as devices to prevent falls;
   (g) electric safety devices in the form of safety switches containing electronic components.
ANNEX VI

Assembly instructions for partly completed machinery

The assembly instructions for partly completed machinery must contain a description of the conditions which must be met with a view to correct incorporation in the final machinery, so as not to compromise safety and health.

The assembly instructions must be written in an official Community language acceptable to the manufacturer of the machinery in which the partly completed machinery will be assembled, or to his authorised representative.
A. Technical file for machinery

This part describes the procedure for compiling a technical file. The technical file must demonstrate that the machinery complies with the requirements of this Directive. It must cover the design, manufacture and operation of the machinery to the extent necessary for this assessment. The technical file must be compiled in one or more official Community languages, except for the instructions for the machinery, for which the special provisions of Annex I, section 1.7.4.1 apply.

1. The technical file shall comprise the following:

   (a) a construction file including:

      — a general description of the machinery,

      — the overall drawing of the machinery and drawings of the control circuits, as well as the pertinent descriptions and explanations necessary for understanding the operation of the machinery,

      — full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the machinery with the essential health and safety requirements,

      — the documentation on risk assessment demonstrating the procedure followed, including:

         (i) a list of the essential health and safety requirements which apply to the machinery,

         (ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, when appropriate, the indication of the residual risks associated with the machinery,

      — the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,

      — any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the manufacturer or his authorised representative,

      — a copy of the instructions for the machinery,

      — where appropriate, the declaration of incorporation for included partly completed machinery and the relevant assembly instructions for such machinery,

      — where appropriate, copies of the EC declaration of conformity of machinery or other products incorporated into the machinery,

      — a copy of the EC declaration of conformity;

   (b) for series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of this Directive.

The manufacturer must carry out necessary research and tests on components, fittings or the completed machinery to determine whether by its design or construction it is capable of being assembled and put into service safely. The relevant reports and results shall be included in the technical file.

2. The technical file referred to in point 1 must be made available to the competent authorities of the Member States for at least 10 years following the date of manufacture of the machinery or, in the case of series manufacture, of the last unit produced.

The technical file does not have to be located in the territory of the Community, nor does it have to be permanently available in material form. However, it must be capable of being assembled and made available within a period of time commensurate with its complexity by the person designated in the EC declaration of conformity.

The technical file does not have to include detailed plans or any other specific information as regards the sub-assemblies used for the manufacture of the machinery unless a knowledge of them is essential for verification of conformity with the essential health and safety requirements.

3. Failure to present the technical file in response to a duly reasoned request by the competent national authorities may constitute sufficient grounds for doubting the conformity of the machinery in question with the essential health and safety requirements.
B. Relevant technical documentation for partly completed machinery

This part describes the procedure for compiling relevant technical documentation. The documentation must show which requirements of this Directive are applied and fulfilled. It must cover the design, manufacture and operation of the partly completed machinery to the extent necessary for the assessment of conformity with the essential health and safety requirements applied. The documentation must be compiled in one or more official Community languages.

It shall comprise the following:

(a) a construction file including:

— the overall drawing of the partly completed machinery and drawings of the control circuits,

— full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the partly completed machinery with the applied essential health and safety requirements,

— the risk assessment documentation showing the procedure followed, including:

(i) a list of the essential health and safety requirements applied and fulfilled,

(ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, where appropriate, the indication of the residual risks,

(iii) the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,

(iv) any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the manufacturer or his authorised representative,

(v) a copy of the assembly instructions for the partly completed machinery;

(b) for series manufacture, the internal measures that will be implemented to ensure that the partly completed machinery remains in conformity with the essential health and safety requirements applied.

The manufacturer must carry out necessary research and tests on components, fittings or the partly completed machinery to determine whether by its design or construction it is capable of being assembled and used safely. The relevant reports and results shall be included in the technical file.

The relevant technical documentation must be available for at least 10 years following the date of manufacture of the partly completed machinery or, in the case of series manufacture, of the last unit produced, and on request presented to the competent authorities of the Member States. It does not have to be located in the territory of the Community, nor does it have to be permanently available in material form. It must be capable of being assembled and presented to the relevant authority by the person designated in the declaration for incorporation.

Failure to present the relevant technical documentation in response to a duly reasoned request by the competent national authorities may constitute sufficient grounds for doubting the conformity of the partly completed machinery with the essential health and safety requirements applied and attested.
ANNEX VIII

Assessment of conformity with internal checks on the manufacture of machinery

1. This Annex describes the procedure by which the manufacturer or his authorised representative, who carries out the obligations laid down in points 2 and 3, ensures and declares that the machinery concerned satisfies the relevant requirements of this Directive.

2. For each representative type of the series in question, the manufacturer or his authorised representative shall draw up the technical file referred to in Annex VII, part A.

3. The manufacturer must take all measures necessary in order that the manufacturing process ensures compliance of the manufactured machinery with the technical file referred to in Annex VII, part A, and with the requirements of this Directive.
ANNEX IX

EC type-examination

EC type-examination is the procedure whereby a notified body ascertains and certifies that a representative model of machinery referred to in Annex IV (hereafter named the type) satisfies the provisions of this Directive.

1. The manufacturer or his authorised representative must, for each type, draw up the technical file referred to in Annex VII, part A.

2. For each type, the application for an EC type-examination shall be submitted by the manufacturer or his authorised representative to a notified body of his choice.

The application shall include:

— the name and address of the manufacturer and, where appropriate, his authorised representative,

— a written declaration that the application has not been submitted to another notified body,

— the technical file.

Moreover, the applicant shall place at the disposal of the notified body a sample of the type. The notified body may ask for further samples if the test programme so requires.

3. The notified body shall:

3.1. examine the technical file, check that the type was manufactured in accordance with it and establish which elements have been designed in accordance with the relevant provisions of the standards referred to in Article 7(2), and those elements whose design is not based on the relevant provisions of those standards;

3.2. carry out or have carried out appropriate inspections, measurements and tests to ascertain whether the solutions adopted satisfy the essential health and safety requirements of this Directive, where the standards referred to in Article 7(2) were not applied;

3.3. where harmonised standards referred to in Article 7(2) were used, carry out or have carried out appropriate inspections, measurements and tests to verify that those standards were actually applied;

3.4. agree with the applicant as to the place where the check that the type was manufactured in accordance with the examined technical file and the necessary inspections, measurements and tests will be carried out.

4. If the type satisfies the provisions of this Directive, the notified body shall issue the applicant with an EC type-examination certificate. The certificate shall include the name and address of the manufacturer and his authorised representative, the data necessary for identifying the approved type, the conclusions of the examination and the conditions to which its issue may be subject.

The manufacturer and the notified body shall retain a copy of this certificate, the technical file and all relevant documents for a period of 15 years from the date of issue of the certificate.

5. If the type does not satisfy the provisions of this Directive, the notified body shall refuse to issue the applicant with an EC type-examination certificate, giving detailed reasons for its refusal. It shall inform the applicant, the other notified bodies and the Member State which notified it. An appeal procedure must be available.

6. The applicant shall inform the notified body which retains the technical file relating to the EC type-examination certificate of all modifications to the approved type. The notified body shall examine these modifications and shall then either confirm the validity of the existing EC type-examination certificate or issue a new one if the modifications are liable to compromise conformity with the essential health and safety requirements or the intended working conditions of the type.

7. The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EC type-examination certificates. On reasoned request, the Commission and the Member States may obtain a copy of the technical file and the results of the examinations carried out by the notified body.

8. Files and correspondence referring to the EC type-examination procedures shall be written in the official Community language(s) of the Member State where the notified body is established or in any other official Community language acceptable to the notified body.
9. Validity of the EC type-examination certificate

9.1. The notified body has the ongoing responsibility of ensuring that the EC type-examination certificate remains valid. It shall inform the manufacturer of any major changes which would have an implication on the validity of the certificate. The notified body shall withdraw certificates which are no longer valid.

9.2. The manufacturer of the machinery concerned has the ongoing responsibility of ensuring that the said machinery meets the corresponding state of the art.

9.3. The manufacturer shall request from the notified body the review of the validity of the EC type-examination certificate every five years.

If the notified body finds that the certificate remains valid, taking into account the state of the art, it shall renew the certificate for a further five years.

The manufacturer and the notified body shall retain a copy of this certificate, of the technical file and of all the relevant documents for a period of 15 years from the date of issue of the certificate.

9.4. In the event that the validity of the EC-type examination certificate is not renewed, the manufacturer shall cease the placing on the market of the machinery concerned.
ANNEX X

Full quality assurance

This Annex describes the conformity assessment of machinery referred to in Annex IV, manufactured using a full quality assurance system, and the procedure whereby a notified body assesses and approves the quality system and monitors its application.

1. The manufacturer must operate an approved quality system for design, manufacture, final inspection and testing, as specified in point 2, and shall be subject to the surveillance referred to in point 3.

2. Quality system

2.1. The manufacturer or his authorised representative shall lodge an application for assessment of his quality system to a notified body of his choice.

The application shall contain:

— the name and address of the manufacturer and, where appropriate, his authorised representative,

— the places of design, manufacture, inspection, testing and storage of the machinery,

— the technical file described in Annex VII, Part A, for one model of each category of machinery referred to in Annex IV which he intends to manufacture,

— the documentation on the quality system,

— a written declaration that the application has not been submitted to another notified body.

2.2. The quality system must ensure conformity of the machinery with the provisions of this Directive. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner, in the form of measures, procedures and written instructions. The documentation on the quality system must permit a uniform interpretation of the procedural and quality measures, such as quality programmes, plans, manuals and records.

It must contain, in particular, an adequate description of:

— the quality objectives, the organisational structure, and the responsibilities and powers of the management with regard to the design and quality of the machinery,

— the technical design specifications, including standards that will be applied and, where the standards referred to in Article 7(2) are not applied in full, the means that will be used to ensure that the essential health and safety requirements of this Directive are fulfilled,

— the design inspection and design verification techniques, processes and systematic actions that will be used when designing machinery covered by this Directive,

— the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,

— the inspections and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,

— the quality records, such as inspection reports and test data, calibration data, and reports on the qualifications of the personnel concerned,

— the means of monitoring the achievement of the required design and quality of the machinery, as well as the effective operation of the quality system.

2.3. The notified body shall assess the quality system to determine whether it satisfies the requirements of point 2.2.

The elements of the quality system which conform to the relevant harmonised standard shall be presumed to conform to the corresponding requirements referred to in point 2.2.

The team of auditors must have at least one member who is experienced in the assessment of the technology of the machinery. The assessment procedure shall include an inspection to be carried out at the manufacturer’s premises. During the assessment, the team of auditors shall carry out a review of the technical files referred to in point 2.1, second paragraph, third indent to ensure their compliance with the relevant health and safety requirements.

The manufacturer or his authorised representative shall be notified of the decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision. An appeal procedure must be available.
2.4. The manufacturer shall undertake to fulfil the obligations arising from the quality system as approved and to ensure that it remains appropriate and effective.

The manufacturer or his authorised representative shall inform the notified body which approved the quality system of any planned change to it.

The notified body shall evaluate the proposed changes and decide whether the modified quality assurance system will continue to satisfy the requirements referred to in point 2.2, or whether a re-assessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3. Surveillance under the responsibility of the notified body

3.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

3.2. The manufacturer shall, for inspection purposes, allow the notified body access to the places of design, manufacture, inspection, testing and storage, and shall provide it with all necessary information, such as:

— the documentation concerning the quality system,
— the quality records provided for in that part of the quality system concerned with design, such as the results of analyses, calculations, tests, etc.,
— the quality records provided for in that part of the quality system concerned with manufacture, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.

3.3. The notified body shall conduct periodic audits to make sure that the manufacturer is maintaining and applying the quality system; it shall provide the manufacturer with an audit report. The frequency of the periodic audits shall be such that a full reassessment is carried out every three years.

3.4. Moreover, the notified body may pay the manufacturer unannounced visits. The need for these additional visits and their frequency will be determined on the basis of a visit monitoring system managed by the notified body. In particular, the following factors will be taken into account in the visits monitoring system:

— the results of previous surveillance visits,
— the need to monitor remedial measures,
— where appropriate, special conditions attaching to approval of the system,
— significant modifications in the organisation of the manufacturing process, measures or techniques.

On the occasion of such visits, the notified body may, if necessary, carry out tests or have them carried out in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if a test was carried out, with a test report.

4. The manufacturer or his authorised representative shall keep available for the national authorities, for a period of ten years from the last date of manufacture:

— the documentation referred to in point 2.1,
— the decisions and reports of the notified body referred to in point 2.4, third and fourth subparagraphs, and in points 3.3 and 3.4.
ANNEX XI

Minimum criteria to be taken into account by Member States for the notification of bodies

1. The body, its director and the staff responsible for carrying out the verification tests shall not be the designer, manufacturer, supplier or installer of machines which they inspect, nor the authorised representative of any of these parties. They shall not become involved, either directly or as authorised representatives, in the design, construction, marketing or maintenance of the machines. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.

2. The body and its staff shall carry out the verification tests with the highest degree of professional integrity and technical competence and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.

3. For each category of machinery for which it is notified, the body must possess personnel with technical knowledge and sufficient and appropriate experience to perform a conformity assessment. It must have the means necessary to complete the technical and administrative tasks connected with implementation of the checks in an appropriate manner; it must also have access to the equipment necessary for the exceptional checks.

4. The staff responsible for inspection shall have:
   — sound technical and vocational training,
   — satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests,
   — the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.

5. The impartiality of inspection staff shall be guaranteed. Their remuneration shall not depend on the number of tests carried out or on the results of such tests.

6. The body shall take out liability insurance unless its liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the tests.

7. The staff of the body shall be bound to observe professional secrecy with regard to all information obtained in carrying out its tasks (except vis-à-vis the competent administrative authorities of the State in which its activities are carried out) under this Directive or any provision of national law giving effect to it.

8. Notified bodies shall participate in coordination activities. They shall also take part directly or be represented in European standardisation, or ensure that they know the situation in respect of relevant standards.

9. Member States may take all necessary measures they regard as necessary in order to ensure that, in the event of cessation of the activities of a notified body, the files of its customers are sent to another body or are made available to the Member State which has notified it.
ANNEX XII

Correlation table (1)

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(1) This table indicates the relation between parts of Directive 98/37/EC and the parts of this Directive that deal with the same subject. However, the content of the correlated parts is not necessarily identical.
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HEALTH AND SAFETY

The Supply of Machinery (Safety) Regulations 2008

Made - - - - ***
Laid before Parliament ***
Coming into force - - 29th December 2009

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The Secretary of State is a Minister designated(a) for the purposes of section 2(2) of the European Communities Act 1972(b) in relation to machinery, including component parts of machines, components or equipment to be attached to or used with machines, and sub-assemblies to be incorporated into or assembled with machines, and in relation to measures relating to lifts and the safety components for use in lifts.

The Secretary of State, in exercise of the powers conferred on him by section 2(2) of that Act, makes the following Regulations.

PART 1
Preliminary

Citation, commencement and revocation

1.—(1) These Regulations may be cited as the Supply of Machinery (Safety) Regulations 2008 and shall come into force on 29th December 2009.

(2) The Regulations listed in the first column of the table in Schedule 1 are revoked to the extent specified in the third column of that table.

Interpretation

2.—(1) In these Regulations—

(a) references to “the Directive” are references to Directive 2006/42/EC of the European Parliament and of the Council on machinery, and amending Directive 95/16/EC(c);

(b) any reference to an Annex designated by a Roman numeral is a reference to the Part of Schedule 2 designated by the corresponding Arabic numeral and reproducing the text of the Annex to the Directive designated by that Roman numeral in the Directive (with minor changes reflecting the use of defined terms and other details of the Directive’s implementation in these Regulations); and

(c) references in Schedule 2 to “provisions of the Directive” include provisions of these Regulations and of the laws of other EEA states which implement the provisions of the Directive.

(2) In these Regulations, unless the context requires otherwise—

“the 1974 Act” means the Health and Safety at Work etc Act 1974(d);

(a) S.I. 2007/1679 (machinery etc) and S.I. 1996/1912 (lifts etc).

(b) 1972 c.68.


(d) 1974 c. 37.
“the 1978 Order” means the Health and Safety at Work (Northern Ireland) Order 1978(a);
“the 1987 Act” means the Consumer Protection Act 1987(b);
“the 1992 Regulations” means the Supply Machinery (Safety) Regulations 1992(c);
“applicable” means, in relation to the application of essential health and safety requirements to any machine, those essential health and safety requirements which are expressed in Part 1 of Schedule 2 (Annex I) as applying either to all machinery or to machinery of a category to which that machine belongs or which has a characteristic that it shares;
“authorised representative” means a person established in an EEA State who has received a written mandate from the manufacturer to perform on his behalf all or part of the obligations and formalities imposed on manufacturers by these Regulations or otherwise in connection with the Directive;
“CE marking” means a mark consisting of the symbol “CE” set out in the form shown in Part 3 of Schedule 2 (Annex 3);
“chains, ropes and webbing” has the meaning given in regulation 4(2)(e);
“the Commission” means the Commission of the European Communities;
“Community directives” includes a law in any part of the United Kingdom which implements a Community directive, but does not include any Community directive, the date for whose implementation by member States has not yet been reached;
“conformity assessment” means the assessment, in accordance with Part 8, Part 9 or Part 10 of Schedule 2 (Annex VIII, IX or X), of whether machinery, or a representative model of machinery, satisfies the applicable requirements of these Regulations, and “conformity assessment procedure” means the procedures specified in any of those Annexes;
“enforcement authority” means—
(a) in Great Britain, subject to sub-paragraph (b)—
   (i) in relation to machinery and partly completed machinery for use at work, the Health and Safety Executive; and
   (ii) in relation to any other machinery or partly completed machinery—
      (aa) within each local weights and measures authority’s area, that authority; or
      (bb) the Secretary of State;
(b) the Office of Rail Regulation where, in Great Britain, the Health and Safety (Enforcing Authority for Railways and Other Guided Transport Systems) Regulations 2006(d) make it the enforcing authority, within the meaning of section 18(7) of the 1974 Act, in relation to machinery for use in the operation of a railway, tramway or any other system of guided transport, as defined in those Regulations;
(c) in Northern Ireland—
   (i) in relation to machinery and partly completed machinery for use at work, the Health and Safety Executive for Northern Ireland; and
   (ii) in relation to any other machinery or partly completed machinery—
      (aa) within each district council’s area, that council; or
      (bb) the Secretary of State;
“essential health and safety requirements” means the requirements set out in sections 1 to 6 of Part 1 of Schedule 2 (Annex I), read in the light of the General Principles set out at the start of Annex I;
“follow”, in relation to a responsible person and a conformity assessment procedure, means the responsible person complying with the requirements which the conformity assessment
procedure, as expressed in Part 8, Part 9 or Part 10 of Schedule 2 (Annex VIII, IX or X), imposes on responsible persons;

“harmonised standard” means a non-binding technical specification adopted by the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) or the European Telecommunications Standards Institute (ETSI), on the basis of a remit issued by the Commission in accordance with the procedures laid down in Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services(a);

“the Health and Safety Executive” means the Health and Safety Executive established under section 10 of the 1974 Act;

“interchangeable equipment” has the meaning given in regulation 4(2)(b);

“lifting accessory” has the meaning given in regulation 4(2)(d);

“machine” means an item of machinery;

“machinery” has the meaning given in regulation 4;

“manufacturer” means, in relation to machinery or partly completed machinery—

(a) a person who designs or manufactures that machinery or partly completed machinery—

(i) with a view to its being placed on the market under his own name or trademark; or

(ii) for his own use in an EEA state; or

(b) if there is no such person, the person who places that machinery or partly completed machinery on the market or puts it into service;

“notified body” means—

(a) a UK notified body;

(b) a person designated as a notified body for the purposes of the Directive by another EEA State and notified by that State to the Commission and the other EEA States under Article 14(1) of the Directive; or

(c) a person recognised for the purpose of carrying out the functions of a notified body under the Directive by inclusion in—

(i) a mutual recognition agreement relating to the Directive; or

(ii) a similar agreement (including a Protocol to a Europe Agreement, or another Agreement, on Conformity Assessment and Acceptance of Industrial Products), which has been concluded between the European Community and a State other than an EEA State;

“notified body criteria” has the meaning given in regulation 16(6);

“notified body designation” has the meaning given in regulations 16(2) and (4);

“partly completed machine” means an item of partly completed machinery;

“partly completed machinery” has the meaning given in regulation 5;

“place on the market” and related expressions have the meaning given in regulation 3;

“published harmonised standard” means a harmonised standard, the references to which have been published in the Official Journal of the European Union;

“put into service” and related expressions have the meaning given in regulation 3;

“removable mechanical transmission device” has the meaning given in regulation 4(2)(f);

“responsible person” means, in relation to machinery or partly completed machinery—

(a) the manufacturer of that machinery or partly completed machinery; or

(b) if there is no such person, the person who places that machinery or partly completed machinery on the market or puts it into service.

(b) the manufacturer’s authorised representative;

“safe” means, in relation to machinery, that when it is properly installed and maintained, and used for the purposes for which it is intended, or under conditions which can reasonably be foreseen, it does not—

(a) endanger the health of, or result in death or injury to, any person; or

(b) where appropriate—

(i) endanger the health of, or result in death or injury to, domestic animals; or

(ii) endanger property,

“safety component” has the meaning given in regulation 4(2)(c);

“UK notified body” has the meaning given in regulation 16(3) and (4);

“use at work” means, in relation to machinery or partly completed machinery, use or operation—

(a) by persons at work (whether exclusively or not); or

(b) otherwise than at work, in non-domestic premises made available to persons at a place where they may use the machinery or partly completed machinery provided for their use there,

and for these purposes, “at work” has the same meaning as it does under or by virtue of section 52 of the 1974 Act for the purposes of Part 1 of that Act.

Placing on the market and putting into service; supplies outside the EEA and showing at trade fairs not covered

3.—(1) In these Regulations, subject to paragraph (2)—

(a) references to placing machinery or partly completed machinery on the market are references to making it available in an EEA State—

(i) for the first time;

(ii) with a view to distribution or use, whether by the person making it available or another; and

(iii) whether for reward or free of charge; and

(b) references to putting any machinery or partly completed machinery into service are references to the first time that it is used for its intended purpose in an EEA State.

(2) For the purposes of these Regulations, machinery or partly completed machinery shall not be regarded as being placed on the market or put into service where—

(a) it does not have affixed to it either the CE marking, or any inscription likely to be confused with the CE marking, and—

(i) it will not be put into service in an EEA state;

(ii) it is imported into an EEA state for re-export to a country which is not an EEA state; or

(iii) it is imported into an EEA state other than in the course of a business by a person who intends to use it other than in the course of a business; or

(b) it is shown at a trade fair, exhibition or other similar demonstration, provided that, where any machinery or partly completed machinery which does not comply with the requirements of these Regulations which would apply to it if it were being placed on the market or put into service is shown at a trade fair, exhibition or other similar demonstration, the responsible person—

(i) displays a notice in relation to it, stating that—

(aa) it does not comply with the requirements of these Regulations; and

(bb) it will not be made available until it does comply with those requirements; and

(ii) takes adequate safety measures to ensure that it does not kill or injure any person.
PART 2
Application

Machinery to which Regulations apply

4.—(1) Subject to regulation 6, provisions of these regulations which refer to “machinery” apply to any product which—

(a) falls within one of the descriptions of products specified in paragraph (2);
(b) does not fall within one of the descriptions of products specified in Schedule 3; and
(c) is placed on the market or put into service on or after 29th December 2009.

(2) The following products are specified for the purposes of paragraph (1)(a)—

(a) assemblies which fall within one of the following descriptions—

(i) assemblies which—

(aa) are fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, and
(bb) consist of linked parts or components, at least one of which moves, and which are joined together for a specific application, regardless of whether or not they are fitted with components to connect them on site or to sources of energy and motion, or are ready to be installed and able to function without being either mounted on a means of transport or installed in a building or structure;

(ii) assemblies which are composed of one or more assemblies, each of which—

(aa) falls within sub-paragraph (i); or
(bb) constitutes partly completed machinery, and which, in order to achieve a common end, are arranged and controlled so that they function as an integral whole;

(iii) assemblies—

(aa) which consist of linked parts or components, at least one of which moves and which are joined together; and
(bb) which are intended for lifting loads, whose only power source is directly applied human effort;

(b) devices which, after the putting into service of machinery or of a tractor, are assembled with that machinery or tractor by the operator himself in order to change its function or attribute a new function, in so far as they are not tools (“interchangeable equipment”);

(c) components—

(i) which serve to fulfil a safety function;
(ii) which are independently placed on the market;
(iii) the failure or malfunction of which endangers the safety of persons; and
(iv) which are not necessary in order for the machinery to function, or for which other components which do not fall within sub-paragraphs (i) to (iii) may be substituted in order for the machinery to function,

(“safety components”, examples of which are listed in Part 5 of Schedule 2 (Annex V));

(d) components or equipment (including slings and their components) which—

(i) are not attached to lifting machinery;
(ii) allow the load to be held;
(iii) are placed between the machinery and the load or on the load itself, or are intended to constitute an integral part of the load; and
(iv) are independently placed on the market
(“lifting accessories”);
(e) chains, ropes and webbing designed and constructed for lifting purposes as part of lifting
machinery or lifting accessories (“chains, ropes and webbing”); and
(f) removable components for transmitting power between self-propelled machinery or a
tractor and another machine by joining them at the first fixed bearing (“removable
mechanical transmission devices”) (when such components are placed on the market with
a guard the components and the guard together shall be regarded as one product).

Partly completed machinery to which Regulations apply

5. Provisions of these Regulations which refer to “partly completed machinery” apply to
assemblies (including drive systems) which—
(a) are almost machinery;
(b) cannot in themselves perform a specific application;
(c) are only intended to be incorporated into or assembled with other machinery or other
partly completed machinery or equipment, thereby forming machinery;
(d) are placed on the market or put into service on or after 29th December 2009; and
(e) are not intended to be incorporated into or assembled with other products to form a
product which falls into one of the descriptions of products specified in Schedule 3.

Disapplication where more specific Community safety rules apply

6. These Regulations do not apply to a machine if, or to the extent that, Community directives
other than the Directive, which apply to it, make more specific provision than the Directive in
connection with the hazards referred to in Part 1 of Schedule 2 (Annex I).

PART 3

General prohibitions and obligations

Supply of machinery: general obligations and prohibition

7.—(1) No responsible person shall place machinery on the market or put it into service unless it
is safe.
(2) Before any responsible person places machinery on the market or puts it into service, he
must—
(a) ensure that it satisfies the applicable essential health and safety requirements;
(b) ensure that the technical file referred to in Part 7 of Schedule 2 (Annex VII), part A is—
(i) prepared in accordance with the requirements of point 1 of Annex VII, part A; and
(ii) made available in accordance with the requirements of point 2 of Annex VII, part A;
(c) provide, in particular, the information necessary to operate it safely, such as instructions;
(d) follow, as appropriate—
(i) the conformity assessment procedure prescribed by regulation 10;
(ii) one of the conformity assessment procedures prescribed by regulation 11; or
(iii) one of the conformity assessment procedures prescribed by regulation 12;
(e) draw up the EC declaration of conformity in accordance with the requirements of Part 2
of Schedule 2 (Annex II), part 1, Section A and ensure that—
(i) a copy of it accompanies the machinery; and
(ii) the original is retained in accordance with the requirements of first paragraph of Annex II, part 2; and

(f) affix the CE marking to the machinery—
   (i) visibly, legibly and indelibly; and
   (ii) as prescribed in Part 3 of Schedule 2 (Annex III).

(3) In order to comply with the requirements of paragraphs (1) and (2), a responsible person must carry out, or procure the carrying out, of all the necessary research and tests on components, fittings or the completed machinery to determine that it is capable of being put into service safely.

(4) For the purposes of paragraph (2)(a), machinery which is manufactured in conformity with a published harmonised standard shall be presumed to comply with the essential health and safety requirements covered by that standard.

Supply of partly completed machinery: general obligations and prohibition

8.—(1) Before any responsible person places partly completed machinery on the market, he must—
   (a) ensure that the relevant technical documentation described in Part 7 of Schedule 2 (Annex VII), part B is—
       (i) prepared in accordance with the requirements of point 1 of Annex VII, part B; and
       (ii) made available in accordance with the requirements of point 2 of Annex VII, part B;
   (b) ensure that assembly instructions are prepared in accordance with Part 6 of Schedule 2 (Annex VI);
   (c) draw up a declaration of incorporation in accordance with Part 2 of Schedule 2 (Annex II), part 1, Section B, and ensure that—
       (i) a copy of it accompanies the machinery; and
       (ii) the original is retained in accordance with the second paragraph of Annex II, part 2.

(2) The assembly instructions and the declaration of incorporation shall accompany partly completed machinery until it is incorporated into machinery.

(3) After partly completed machinery is incorporated into machinery its assembly instructions and declaration of incorporation shall form part of the technical file for that machinery.

Putting machinery into service

9. No person who is not a responsible person shall put machinery into service unless it satisfies the applicable essential health and safety requirements and is safe.

Conformity assessment procedures

Machinery not referred to in Annex IV

10. If machinery falls within a category which is not referred to in Part 4 of Schedule 2 (Annex IV), the responsible person shall follow the conformity assessment procedure with internal checks on the manufacture of machinery prescribed in Part 8 of Schedule 2 (Annex VIII) in respect of it.

Annex IV machinery manufactured fully in accordance with published harmonised standards and fully covered by such standards

11.—(1) If machinery—
   (a) falls within a category which is referred to in Part 4 of Schedule 2 (Annex IV); and
   (b) both of the conditions specified in paragraph (2) are satisfied in respect of it,
the responsible person shall follow one of the conformity assessment procedures specified in paragraph (3) in respect of that machinery.

(2) The conditions specified in this paragraph are—

(a) that the machinery is manufactured in accordance with published harmonised standards; and

(b) that the published harmonised standards in accordance with which it is manufactured cover all the applicable essential health and safety requirements.

(3) The conformity assessment procedures specified in this paragraph are—

(a) the conformity assessment procedure with internal checks on the manufacture of machinery prescribed in Part 8 of Schedule 2 (Annex VIII);

(b) the EC type-examination procedure prescribed in Part 9 of Schedule 2 (Annex IX) and the internal checks on the manufacture of machinery prescribed in Annex VIII, point 3; or

(c) the full quality assurance procedure prescribed in Part 10 of Schedule 2 (Annex X).

Annex IV machinery not manufactured fully in accordance with published harmonised standards or not fully covered by such standards

12.—(1) If machinery—

(a) falls within a category which is referred to in Part 4 of Schedule 2 (Annex IV); and

(b) one of the conditions specified in paragraph (2) is satisfied in respect of it,

the responsible person shall follow one of the conformity assessment procedures specified in paragraph (3).

(2) The conditions specified in this paragraph are—

(a) that the machinery is not manufactured in accordance with published harmonised standards;

(b) that the machinery is only partly manufactured in accordance with published harmonised standards;

(c) that the published harmonised standards in accordance with which the machinery is manufactured do not cover all the applicable essential health and safety requirements; or

(d) that no harmonised standards exist for the machinery.

(3) The conformity assessment procedures specified in this paragraph are—

(a) the EC type-examination procedure prescribed in Part 9 of Schedule 2 (Annex IX) and the internal checks on the manufacture of machinery prescribed in Part 8 of Schedule 2 (Annex VIII), point 3; or

(b) the full quality assurance procedure prescribed in Part 10 of Schedule 2 (Annex X).

PART 4
CE Marking

CE-marked machinery to be taken to comply with Regulations

13.—(1) Subject to paragraph (2), the fact that machinery bears the CE marking and is accompanied by an EC declaration of conformity which complies with Part 2 of Schedule 2 (Annex II), part 1, section A shall be prima facie evidence that the machinery complies with all the provisions of these Regulations.

(2) Paragraph (1) does not apply in relation to an enforcement authority where the responsible person fails, or refuses, to make the technical file or a copy of it available in accordance with point 2 of Part 7 of Schedule 2 (Annex VII), part A.
Machinery covered by more than one Directive

14.---(1) Subject to paragraph (2), where machinery falls within the scope of a Community directive other than the Directive, (“the other Directive”), no person shall affix a CE marking to it unless the relevant requirements of the other Directive are also satisfied.

(2) Where——

(a) the other Directive includes a provision allowing the responsible person to choose, during a transitional period that has not ended, the system to be applied;

(b) the responsible person takes advantage of this option; and

(c) the particulars of the Directive or the other Directive which he has chosen to apply, as published in the Official Journal of the European Union, are given in the EC declaration of conformity,

the affixing of the CE marking shall indicate that the machinery conforms only with the provisions of the Directive or the other Directive which the responsible person has chosen to apply.

Protection of CE marking

15.---(1) No person shall affix to machinery any marking, sign or inscription which is likely to mislead any other person as to the meaning or form of the CE marking (or both).

(2) Other markings may be affixed to machinery which bears the CE marking only if the visibility, legibility or meaning of the CE marking is not impaired as a result.

PART 5

Notified bodies

Designation and monitoring of UK notified bodies

16.---(1) The Secretary of State may designate a person to carry out conformity assessment.

(2) Subject to paragraph (4), any such designation (a “notified body designation”) shall be made in accordance with this regulation.

(3) A person in respect of whom—

(a) a notified body designation has been made under this regulation; and

(b) whose designation has been notified by the Secretary of State to the Commission and the other EEA states under Article 14(1) of the Directive,

is a “UK notified body” to the extent that that designation remains in effect.

(4) If a person holds an appointment as a United Kingdom approved body under the 1992 Regulations which has been notified to the Commission and the other EEA states under Article 9(1) of Directive 98/37/EC and has not been terminated—

(a) the appointment—

(i) is a “notified body designation” for the purposes of these Regulations; and

(ii) shall be varied in accordance with regulation 17 to the extent that it is necessary or expedient to vary it to take account of the repeal of Directive 98/37/EC and the revocation of the 1992 Regulations and their replacement by the Directive and these Regulations; and

(b) that person is a “UK notified body” to the extent that the appointment remains in effect.

(5) Except where paragraph (4) applies, any person wishing to become a UK notified body must apply to the Secretary of State for designation under this regulation.

(6) The Secretary of State shall not make a notified body designation unless he is satisfied that the person in respect of whom it is to be made meets the criteria specified in Part 11 of Schedule 2 (Annex XI) (the “notified body criteria”).
(7) A person who meets the criteria laid down in a published harmonised standard shall be presumed to meet that part of the notified body criteria which corresponds to the criteria in that standard.

(8) A notified body designation—
(a) shall be in writing;
(b) shall specify the conformity assessment procedures that the person designated may carry out;
(c) may relate to all the categories of machinery listed in Part 4 of Schedule 2 (Annex IV) or to such of those categories as the Secretary of State from time to time determines;
(d) may designate a person as a notified body for a specified period; and
(e) may be made subject to such other conditions as are specified in the designation, including conditions which are to apply upon or following termination of the designation.

(9) In making a notified body designation the Secretary of State may have regard (in addition to the notified body criteria) to any matter which appears to him to be relevant.

(10) The Secretary of State shall, from time to time, publish a list of notified bodies, identifying, in the case of each UK notified body, the description of machinery for which that notified body is designated.

(11) The Secretary of State shall, from time to time, carry out an inspection of each UK notified body with a view to verifying that it—
(a) meets the notified body criteria;
(b) complies with any condition to which its designation is subject; and
(c) complies with these Regulations.

(12) A UK notified body shall comply with any request of the Secretary of State to provide information relevant to determining its compliance with the notified body criteria, these Regulations, or any condition to which its designation is subject.

**Duration, variation and termination of designations**

17.—(1) A notified body designation which does not designate a person as a UK notified body for a specified period shall have effect until such time as it is terminated under paragraph (4).

(2) A notified body designation which designates a person as a UK notified body for a specified period shall expire in accordance with its terms unless the period so specified is extended or shortened under paragraph (3) before the date on which it had been due to expire.

(3) The Secretary of State may vary a notified body designation if—
(a) the UK notified body so requests; or
(b) it appears to him necessary or expedient to do so.

(4) The Secretary of State may terminate a notified body designation—
(a) on the expiry of 90 days’ notice in writing at the request of the UK notified body;
(b) if it appears to him that any condition of the designation is not complied with; or
(c) if in his opinion the UK notified body ceases to satisfy the notified body criteria.

(5) Where the Secretary of State is minded to—
(a) vary a notified body designation in accordance with paragraph (3)(b); or
(b) terminate a notified body designation under paragraph (4)(b) or (c),
he shall—
(i) give notice in writing to the UK notified body of his reasons; and
(ii) give it the opportunity to make representations within a period of 21 days from the date of that notice and consider any representations made to him within that period.
(6) If a notified body designation is terminated under paragraph (4), the Secretary of State may—

(a) authorise another UK notified body to take over the functions of the UK notified body whose designation has been terminated in respect of such cases as he specifies; and

(b) give such directions as he considers appropriate (either to the UK notified body whose designation has been terminated or to another UK notified body) for the purposes of making arrangements for the determination of outstanding applications.

Functions of UK notified bodies

18.—(1) Subject to the terms of their notified body designations and paragraph (2), UK notified bodies shall carry out the functions of notified bodies specified in Parts 9 and 10 of Schedule 2 (Annexes IX and X).

(2) A UK notified body shall not be obliged to carry out these functions where—

(a) the documents submitted to it in relation to the carrying out of any such function (other than the instructions for the machinery) are not in English or another language acceptable to the body;

(b) the responsible person has not submitted with its application the amount of the fee which the body requires to be submitted with the application; or

(c) the body reasonably believes that, having regard to the number of outstanding applications made to it in relation to its appointment under these Regulations, it will be unable to carry out the required work within 3 months of receiving the application.

(3) If, having issued a certificate to a responsible person under Annex IX or an approval to a manufacturer under Annex X, a UK notified body finds—

(a) that the manufacturer has, after the issue of that certificate or approval, failed to satisfy applicable requirements of these Regulations in respect of the machinery to which the certificate or approval relates (whether or not such failure is continuing); or

(b) that the certificate or approval should not have been issued,

it shall proceed in accordance with paragraph (4).

(4) Where paragraph (3) applies, the UK notified body concerned shall—

(a) consider—

(i) what corrective action, if any, the manufacturer should take in the light of its findings; and

(ii) whether, and, if so, on what terms, the certificate or approval should be suspended, withdrawn, or made subject to restrictions;

(b) communicate to the manufacturer the conclusions it has provisionally reached under paragraph (a), and the reasons for those conclusions, and invite the manufacturer to respond to them within a reasonable period of time;

(c) make a determination on the matters specified in paragraph (a), including provision for the suspension or withdrawal of a certificate or approval, or making it subject to restrictions, if it considers the taking of any such action appropriate, having regard to—

(i) the manufacturer’s response;

(ii) the principle of proportionality; and

(iii) paragraph (6); and

(d) communicate the determination, with a detailed statement of the reasons for it, to the manufacturer.

(5) Where a UK notified body, acting under paragraph (4)—

(a) suspends or withdraws a certificate, or makes it subject to restrictions; or

(b) considers that action by an enforcement authority may prove necessary in connection with the machinery which is the subject of its determination,
it shall communicate its determination under that paragraph to the enforcement authorities and the Secretary of State (if he is not an enforcement authority in relation to the machinery concerned).

(6) In making a determination under paragraph (4), a UK notified body shall not suspend or withdraw a certificate or approval, or make it subject to restrictions, if the manufacturer ensures compliance with the applicable requirements of these Regulations by means of appropriate corrective measures.

(7) The provisions of Schedule 4 shall have effect in relation to any appeal by a manufacturer against a determination which a UK notified body has made under paragraph (4).

Fees

19.—(1) A UK notified body may charge such fees in connection with, or incidental to, carrying out its functions under regulation 18 as it may determine; provided that such fees shall not exceed the sum of—

(a) the costs incurred or to be incurred by the body in performing the relevant functions; plus
(b) an amount on account of profit which is reasonable in the circumstances having regard to—
(i) the character and extent of the work done or to be done by the body on behalf of the responsible person; and
(ii) the commercial rate normally charged on account of profit for that work or similar work.

(2) The power in paragraph (1) includes the power to require the payment of fees or a reasonable estimate of fees in advance of carrying out the work required by the responsible person.

PART 6
Enforcement

General duties and powers of enforcement authorities

20.—(1) Schedule 5, which makes provision about the general duties and powers of the enforcement authorities, shall have effect.

(2) Where an enforcement authority has reasonable grounds for suspecting that the machinery is deficient as regards CE marking, but does not have reasonable grounds for suspecting it is unsafe, the enforcement authority may take action under the following provisions as they are applied by Schedule 5—

(a) in Great Britain in relation to machinery for use at work, section 20 of the 1974 Act;
(b) in Northern Ireland in relation to machinery for use at work, Article 22 of the 1978 Order; and
(c) in relation to other machinery, section 29 of the 1987 Act,

but no other action may be taken pursuant to Schedule 5 and no proceedings may be brought pursuant to regulation 21 below in respect of that machinery until the enforcement authority has given the responsible person notice in writing in accordance with paragraph (4) and he has failed to comply with its requirements.

(3) For the purposes of this regulation, machinery is deficient as regards CE marking whenever the CE marking—

(a) is not affixed in circumstances in which it should have been affixed, or
(b) is affixed in circumstances in which it should not have been affixed.

(4) Notice which is given under paragraph (2) above shall—

(a) identify the machinery which the enforcement authority suspects is deficient as regards CE marking within the meaning of this regulation;
(b) specify the nature of the suspected deficiency and the grounds for the enforcement authority’s suspicion;

(c) require the responsible person—

(i) to secure that any machinery to which the notice relates conforms with the provisions of these Regulations concerning the affixation of the CE marking within such period as may be specified in the notice; or

(ii) to provide evidence within that period, to the satisfaction of the enforcement authority, that the machinery is not deficient as regards CE marking; and

(d) warn the responsible person that if the deficiency continues beyond the period specified in the notice, or if satisfactory evidence that the machinery is not deficient as regards CE marking has not been provided within that period, further action may be taken under these Regulations.

Offences and penalties

21.—(1) Any person who contravenes or fails to comply with a requirement of regulations 7, 8, 9, 10, 11, 12 or 15 is guilty of an offence.

(2) Subject to paragraph (3), a person guilty of an offence under paragraph (1) shall be liable—

(a) on summary conviction, to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding three months or to both; and

(b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

(3) A person who is guilty of an offence by virtue of his contravention or failure to comply with—

(a) regulation 7(2)(b)(ii) or (e)(ii),

(b) regulation 8(1)(a)(ii) or (c)(ii), or

(c) regulation 15,

shall be liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Defence of due diligence

22.—(1) Subject to the following provisions of this regulation, in proceedings against a person for an offence under these Regulations, it is a defence for that person to show that he took all reasonable steps and exercised all due diligence to avoid committing the offence.

(2) Where, in proceedings against a person for such an offence, the defence provided by paragraph (1) involves an allegation that the commission of the offence was due to—

(a) the act or default of another; or

(b) reliance on information given by another,

that person shall not, without the leave of the court, be entitled to rely on the defence, unless, not less than seven clear days before the hearing of the proceedings (or, in Scotland, the trial diet), he has served a notice in accordance with paragraph (3) on the person bringing the proceedings.

(3) A notice served under paragraph (2) shall contain such information identifying or assisting in the identification of the person who committed the act or default or gave the information as is in the possession of the person serving the notice at the time he serves it.

(4) A person shall not be entitled to rely on the defence provided by paragraph (1) by reason of his reliance on information supplied by another, unless he shows it was reasonable in all the circumstances for him to have relied on the information, having regard in particular to—

(a) the steps which he took, and those which might reasonably have been taken, for the purpose of verifying the information; and

(b) whether he had any reason to disbelieve the information.
Liability of persons other than the principal offender

23.—(1) Where the commission by a person of an offence under these Regulations is due to the act or default of another person in the course of any business of his, that other person shall be guilty of the offence and may be proceeded against and punished, whether or not proceedings are taken against the first person.

(2) Where a body corporate commits an offence and it is proved that the offence was committed—
   (a) with the consent or connivance of an officer of the body corporate; or
   (b) as a result of the negligence of an officer of the body corporate,
   the officer, as well as the body corporate, shall be guilty of the offence.

(3) In paragraph (2), a reference to an officer of a body corporate includes a reference to—
   (a) a director, manager, secretary or other similar officer of the body corporate;
   (b) a person purporting to act as a director, manager, secretary or other similar officer; and
   (c) if the affairs of the body corporate are managed by its members, a member.

(4) In this regulation, references to a “body corporate” include references to a partnership in Scotland, and in relation to such partnership, any reference to a director, manager, secretary or other similar officer of a body corporate is a reference to a partner.

PART 7
Miscellaneous

Amendment of the Lifts Regulations 1997

24. The amendments to the Lifts Regulations 1997(a) specified in Schedule 6 shall have effect.

Other amendments consequential on the replacement of Directive 98/37/EC and the 1992 Regulations by the Directive and these Regulations

25. The amendments specified in Schedule 7 shall have effect.

Consequential disapplication of domestic health and safety law

26.—(1) Subject to paragraph (3), any requirement which—
   (a) is imposed by or under any of the enactments (relating to various aspects of the safety of machinery) specified in paragraph (2); and
   (b) but for the provisions of this paragraph, would have to be satisfied by or in respect of machinery if it is to be lawfully placed on the market or put into service,
   is disapplied.

(2) The enactments referred to in paragraph (1)(a) are—
   (a) section 83 of the Mines and Quarries Act 1954(b);
   (b) section 85(1) of the Mines Act (Northern Ireland) 1969(c);
   (c) regulation 3(3) of the Coal and Other Mines (Locomotives) Regulations 1956(d);
   (d) regulation 52 of the Miscellaneous Mines (General) Regulations 1956(e);

(b) 1954 c.70.
(c) 1969 c.6.
(d) S.I. 1956/1771.
(e) S.I. 1956/1778
(e) regulation 11 of the Coal Mines (Firedamp Drainage) Regulations 1960(a);
(f) in the Docks Regulations 1988(b), regulation 13(1)(a), (b), and (c), the words “or assembled” in regulation 13(1)(d) and regulations 13(2)(b), (c) and (d);
(g) in the Docks Regulations (Northern Ireland) 1989(c), regulation 13(1)(a), (b), and (c), the words “or assembled” in regulation 13(1)(d) and regulations 13(2)(b), (c) and (d);
(h) in the Electricity at Work Regulations 1989(d) and in the Electricity at Work Regulations (Northern Ireland) 1991(e) respectively, regulation 26; and
(i) in the Regulations specified in the first column of Schedule 8, the regulations specified in the third column of that Schedule.

(3) This regulation does not affect the application of the enactments listed in paragraph (2) to machinery after it has been placed on the market or put into service.

Machinery which is electrical equipment

27. The Electrical Equipment (Safety) Regulations 1994(f) are disapplied in respect of machinery which is electrical equipment within the meaning of those Regulations in so far as the risks as to the safety of such equipment are not mainly of electrical origin.

[Minister’s name]
[Minister’s title]

Date Department for Business, Enterprise & Regulatory Reform

SCHEDULE 1

REGULATIONS REVOKED

<table>
<thead>
<tr>
<th>Regulations</th>
<th>Reference</th>
<th>Extent of revocation</th>
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<tr>
<td>The All-Terrain Motor Vehicles (Safety) Regulations 1989</td>
<td>S.I. 1989/2288</td>
<td>Regulations 4, 5 and 6</td>
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<tr>
<td>The Supply of Machinery Regulations 1992</td>
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<td>The Supply of Machinery (Amendment) Regulations 2005</td>
<td>S.I. 2005/831</td>
<td>The whole Regulations</td>
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(a) S.I. 1960/1015.
(b) S.I. 1988/1655.
(c) S.R. 1989 No. 320.
(d) S.I. 1989/635.
(e) S.R. 1991 No. 13.
ANNEXES TO THE DIRECTIVE

PART 1

Annex I: Essential health and safety requirements relating to the design and construction of machinery

GENERAL PRINCIPLES

1. The manufacturer of machinery or his authorised representative must ensure that a risk assessment is carried out in order to determine the health and safety requirements which apply to the machinery. The machinery must then be designed and constructed taking into account the results of the risk assessment.

   By the iterative process of risk assessment and risk reduction referred to above, the responsible person shall:

   — determine the limits of the machinery, which include the intended use and any reasonably foreseeable misuse thereof,

   — identify the hazards that can be generated by the machinery and the associated hazardous situations,

   — estimate the risks, taking into account the severity of the possible injury or damage to health and the probability of its occurrence,

   — evaluate the risks, with a view to determining whether risk reduction is required, in accordance with the objective of the Directive,

   — eliminate the hazards or reduce the risks associated with these hazards by application of protective measures, in the order of priority established in section 1.1.2(b) of this Annex.

2. The obligations laid down by the essential health and safety requirements only apply when the corresponding hazard exists for the machinery in question when it is used under the conditions foreseen by the responsible person or in foreseeable abnormal situations. In any event, the principles of safety integration referred to in section 1.1.2 of this Annex and the obligations concerning marking of machinery and instructions referred to in sections 1.7.3 and 1.7.4 of this Annex apply.

3. The essential health and safety requirements laid down in this Annex are mandatory. However, taking into account the state of the art, it may not be possible to meet the objectives set by them. In that event, the machinery must, as far as possible, be designed and constructed with the purpose of approaching these objectives.

4. This Annex is organised in several sections. The first section has a general scope and is applicable to all kinds of machinery. The other parts refer to certain kinds of more specific hazards. Nevertheless, it is essential to examine the whole of this Annex in order to be sure of meeting all the applicable essential requirements. When machinery is being designed, the requirements of the general part and the requirements of one or more of the other parts shall be taken into account, depending on the results of the risk assessment carried out in accordance with point 1 of these General Principles.
1. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

1.1. GENERAL REMARKS

1.1.1. Definitions

For the purpose of this Annex:

(a) “hazard” means a potential source of injury or damage to health;

(b) “danger zone” means any zone within and/or around machinery in which a person is subject to a risk to his health or safety;

(c) “exposed person” means any person wholly or partially in a danger zone;

(d) “operator” means the person or persons installing, operating, adjusting, maintaining, cleaning, repairing or moving machinery;

(e) “risk” means a combination of the probability and the degree of an injury or damage to health that can arise in a hazardous situation;

(f) “guard” means a part of the machinery used specifically to provide protection by means of a physical barrier;

(g) “protective device” means a device (other than a guard) which reduces the risk, either alone or in conjunction with a guard;

(h) “intended use” means the use of machinery in accordance with the information provided in the instructions for use;

(i) “reasonably foreseeable misuse” means the use of machinery in a way not intended in the instructions for use, but which may result from readily predictable human behaviour.

1.1.2. Principles of safety integration

(a) Machinery must be designed and constructed so that it is fitted for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen but also taking into account any reasonably foreseeable misuse thereof.

The aim of measures taken must be to eliminate any risk throughout the foreseeable lifetime of the machinery including the phases of transport, assembly, dismantling, disabling and scrapping.

(b) In selecting the most appropriate methods, the responsible person must apply the following principles, in the order given:

— eliminate or reduce risks as far as possible (inherently safe machinery design and construction),

— take the necessary protective measures in relation to risks that cannot be eliminated,

— inform users of the residual risks due to any shortcomings of the protective measures adopted, indicate whether any particular training is required and specify any need to provide personal protective equipment.

(c) When designing and constructing machinery and when drafting the instructions, the responsible person must envisage not only the intended use of the machinery but also any reasonably foreseeable misuse thereof.
The machinery must be designed and constructed in such a way as to prevent abnormal use if such use would engender a risk. Where appropriate, the instructions must draw the user’s attention to ways – which experience has shown might occur – in which the machinery should not be used.

(d) Machinery must be designed and constructed to take account of the constraints to which the operator is subject as a result of the necessary or foreseeable use of personal protective equipment.

(e) Machinery must be supplied with all the special equipment and accessories essential to enable it to be adjusted, maintained and used safely.

1.1.3. Materials and products

The materials used to construct machinery or products used or created during its use must not endanger persons’ safety or health. In particular, where fluids are used, machinery must be designed and constructed to prevent risks due to filling, use, recovery or draining.

1.1.4. Lighting

Machinery must be supplied with integral lighting suitable for the operations concerned where the absence thereof is likely to cause a risk despite ambient lighting of normal intensity.

Machinery must be designed and constructed so that there is no area of shadow likely to cause nuisance, that there is no irritating dazzle and that there are no dangerous stroboscopic effects on moving parts due to the lighting.

Internal parts requiring frequent inspection and adjustment, and maintenance areas, must be provided with appropriate lighting.

1.1.5. Design of machinery to facilitate its handling

Machinery, or each component part thereof, must:

— be capable of being handled and transported safely,

— be packaged or designed so that it can be stored safely and without damage.

During the transportation of the machinery and/or its component parts, there must be no possibility of sudden movements or of hazards due to instability as long as the machinery and/or its component parts are handled in accordance with the instructions.

Where the weight, size or shape of machinery or its various component parts prevents them from being moved by hand, the machinery or each component part must:

— either be fitted with attachments for lifting gear, or

— be designed so that it can be fitted with such attachments, or

— be shaped in such a way that standard lifting gear can easily be attached.

Where machinery or one of its component parts is to be moved by hand, it must:

— either be easily moveable, or

— be equipped for picking up and moving safely.

Special arrangements must be made for the handling of tools and/or machinery parts which, even if lightweight, could be hazardous.
1.1.6. **Ergonomics**

Under the intended conditions of use, the discomfort, fatigue and physical and psychological stress faced by the operator must be reduced to the minimum possible, taking into account ergonomic principles such as:

— allowing for the variability of the operator’s physical dimensions, strength and stamina,
— providing enough space for movements of the parts of the operator’s body,
— avoiding a machine-determined work rate,
— avoiding monitoring that requires lengthy concentration,
— adapting the man/machinery interface to the foreseeable characteristics of the operators.

1.1.7. **Operating positions**

The operating position must be designed and constructed in such a way as to avoid any risk due to exhaust gases and/or lack of oxygen.

If the machinery is intended to be used in a hazardous environment presenting risks to the health and safety of the operator or if the machinery itself gives rise to a hazardous environment, adequate means must be provided to ensure that the operator has good working conditions and is protected against any foreseeable hazards.

Where appropriate, the operating position must be fitted with an adequate cabin designed, constructed and/or equipped to fulfil the above requirements. The exit must allow rapid evacuation. Moreover, when applicable, an emergency exit must be provided in a direction which is different from the usual exit.

1.1.8. **Seating**

Where appropriate and where the working conditions so permit, work stations constituting an integral part of the machinery must be designed for the installation of seats.

If the operator is intended to sit during operation and the operating position is an integral part of the machinery, the seat must be provided with the machinery.

The operator’s seat must enable him to maintain a stable position. Furthermore, the seat and its distance from the control devices must be capable of being adapted to the operator.

If the machinery is subject to vibrations, the seat must be designed and constructed in such a way as to reduce the vibrations transmitted to the operator to the lowest level that is reasonably possible. The seat mountings must withstand all stresses to which they can be subjected. Where there is no floor beneath the feet of the operator, footrests covered with a slip-resistant material must be provided.

1.2. **CONTROL SYSTEMS**

1.2.1. **Safety and reliability of control systems**

Control systems must be designed and constructed in such a way as to prevent hazardous situations from arising. Above all, they must be designed and constructed in such a way that:

— they can withstand the intended operating stresses and external influences,
— a fault in the hardware or the software of the control system does not lead to hazardous situations,
— errors in the control system logic do not lead to hazardous situations,
— reasonably foreseeable human error during operation does not lead to hazardous situations.

Particular attention must be given to the following points:
— the machinery must not start unexpectedly,
— the parameters of the machinery must not change in an uncontrolled way, where such change may lead to hazardous situations,
— the machinery must not be prevented from stopping if the stop command has already been given,
— no moving part of the machinery or piece held by the machinery must fall or be ejected,
— automatic or manual stopping of the moving parts, whatever they may be, must be unimpeded,
— the protective devices must remain fully effective or give a stop command,
— the safety-related parts of the control system must apply in a coherent way to the whole of an assembly of machinery and/or partly completed machinery.

For cable-less control, an automatic stop must be activated when correct control signals are not received, including loss of communication.

1.2.2. Control devices

Control devices must be:
— clearly visible and identifiable, using pictograms where appropriate,
— positioned in such a way as to be safely operated without hesitation or loss of time and without ambiguity,
— designed in such a way that the movement of the control device is consistent with its effect,
— located outside the danger zones, except where necessary for certain control devices such as an emergency stop or a teach pendant,
— positioned in such a way that their operation cannot cause additional risk,
— designed or protected in such a way that the desired effect, where a hazard is involved, can only be achieved by a deliberate action,
— made in such a way as to withstand foreseeable forces; particular attention must be paid to emergency stop devices liable to be subjected to considerable forces.

Where a control device is designed and constructed to perform several different actions, namely where there is no one-to-one correspondence, the action to be performed must be clearly displayed and subject to confirmation, where necessary.

Control devices must be so arranged that their layout, travel and resistance to operation are compatible with the action to be performed, taking account of ergonomic principles.

Machinery must be fitted with indicators as required for safe operation. The operator must be able to read them from the control position.
From each control position, the operator must be able to ensure that no-one is in the danger zones, or the control system must be designed and constructed in such a way that starting is prevented while someone is in the danger zone.

If neither of these possibilities is applicable, before the machinery starts, an acoustic and/or visual warning signal must be given. The exposed persons must have time to leave the danger zone or prevent the machinery starting up.

If necessary, means must be provided to ensure that the machinery can be controlled only from control positions located in one or more predetermined zones or locations.

Where there is more than one control position, the control system must be designed in such a way that the use of one of them precludes the use of the others, except for stop controls and emergency stops.

When machinery has two or more operating positions, each position must be provided with all the required control devices without the operators hindering or putting each other into a hazardous situation.

1.2.3. Starting

It must be possible to start machinery only by voluntary actuation of a control device provided for the purpose.

The same requirement applies:

— when restarting the machinery after a stoppage, whatever the cause,

— when affecting a significant change in the operating conditions.

However, the restarting of the machinery or a change in operating conditions may be effected by voluntary actuation of a device other than the control device provided for the purpose, on condition that this does not lead to a hazardous situation.

For machinery functioning in automatic mode, the starting of the machinery, restarting after a stoppage, or a change in operating conditions may be possible without intervention, provided this does not lead to a hazardous situation.

Where machinery has several starting control devices and the operators can therefore put each other in danger, additional devices must be fitted to rule out such risks. If safety requires that starting and/or stopping must be performed in a specific sequence, there must be devices which ensure that these operations are performed in the correct order.

1.2.4. Stopping

1.2.4.1. Normal stop

Machinery must be fitted with a control device whereby the machinery can be brought safely to a complete stop.

Each workstation must be fitted with a control device to stop some or all of the functions of the machinery, depending on the existing hazards, so that the machinery is rendered safe.

The machinery’s stop control must have priority over the start controls.

Once the machinery or its hazardous functions have stopped, the energy supply to the actuators concerned must be cut off.
1.2.4.2. Operational stop

Where, for operational reasons, a stop control that does not cut off the energy supply to the actuators is required, the stop condition must be monitored and maintained.

1.2.4.3. Emergency stop

Machinery must be fitted with one or more emergency stop devices to enable actual or impending danger to be averted.

The following exceptions apply:

— machinery in which an emergency stop device would not lessen the risk, either because it would not reduce the stopping time or because it would not enable the special measures required to deal with the risk to be taken,
— portable hand-held and/or hand-guided machinery.

The device must:

— have clearly identifiable, clearly visible and quickly accessible control devices,
— stop the hazardous process as quickly as possible, without creating additional risks,
— where necessary, trigger or permit the triggering of certain safeguard movements.

Once active operation of the emergency stop device has ceased following a stop command, that command must be sustained by engagement of the emergency stop device until that engagement is specifically overridden; it must not be possible to engage the device without triggering a stop command; it must be possible to disengage the device only by an appropriate operation, and disengaging the device must not restart the machinery but only permit restarting.

The emergency stop function must be available and operational at all times, regardless of the operating mode.

Emergency stop devices must be a back-up to other safeguarding measures and not a substitute for them.

1.2.4.4. Assembly of machinery

In the case of machinery or parts of machinery designed to work together, the machinery must be designed and constructed in such a way that the stop controls, including the emergency stop devices, can stop not only the machinery itself but also all related equipment, if its continued operation may be dangerous.

1.2.5. Selection of control or operating modes

The control or operating mode selected must override all other control or operating modes, with the exception of the emergency stop.

If machinery has been designed and constructed to allow its use in several control or operating modes requiring different protective measures and/or work procedures, it must be fitted with a mode selector which can be locked in each position. Each position of the selector must be clearly identifiable and must correspond to a single operating or control mode.

The selector may be replaced by another selection method which restricts the use of certain functions of the machinery to certain categories of operator.
If, for certain operations, the machinery must be able to operate with a guard displaced or removed and/or a protective device disabled, the control or operating mode selector must simultaneously:

— disable all other control or operating modes,
— permit operation of hazardous functions only by control devices requiring sustained action,
— permit the operation of hazardous functions only in reduced risk conditions while preventing hazards from linked sequences,
— prevent any operation of hazardous functions by voluntary or involuntary action on the machine’s sensors.

If these four conditions cannot be fulfilled simultaneously, the control or operating mode selector must activate other protective measures designed and constructed to ensure a safe intervention zone.

In addition, the operator must be able to control operation of the parts he is working on from the adjustment point.

1.2.6. **Failure of the power supply**

The interruption, the re-establishment after an interruption or the fluctuation in whatever manner of the power supply to the machinery must not lead to dangerous situations.

Particular attention must be given to the following points:

— the machinery must not start unexpectedly,
— the parameters of the machinery must not change in an uncontrolled way when such change can lead to hazardous situations,
— the machinery must not be prevented from stopping if the command has already been given,
— no moving part of the machinery or piece held by the machinery must fall or be ejected,
— automatic or manual stopping of the moving parts, whatever they may be, must be unimpeded,
— the protective devices must remain fully effective or give a stop command.

1.3. **PROTECTION AGAINST MECHANICAL HAZARDS**

1.3.1. **Risk of loss of stability**

Machinery and its components and fittings must be stable enough to avoid overturning, falling or uncontrolled movements during transportation, assembly, dismantling and any other action involving the machinery.

If the shape of the machinery itself or its intended installation does not offer sufficient stability, appropriate means of anchorage must be incorporated and indicated in the instructions.

1.3.2. **Risk of break-up during operation**

The various parts of machinery and their linkages must be able to withstand the stresses to which they are subject when used.

The durability of the materials used must be adequate for the nature of the working environment foreseen by the responsible person, in particular as regards the phenomena of fatigue, ageing, corrosion and abrasion.
The instructions must indicate the type and frequency of inspections and maintenance required for safety reasons. They must, where appropriate, indicate the parts subject to wear and the criteria for replacement.

Where a risk of rupture or disintegration remains despite the measures taken, the parts concerned must be mounted, positioned and/or guarded in such a way that any fragments will be contained, preventing hazardous situations.

Both rigid and flexible pipes carrying fluids, particularly those under high pressure, must be able to withstand the foreseen internal and external stresses and must be firmly attached and/or protected to ensure that no risk is posed by a rupture.

Where the material to be processed is fed to the tool automatically, the following conditions must be fulfilled to avoid risks to persons:

— when the workpiece comes into contact with the tool, the latter must have attained its normal working condition,

— when the tool starts and/or stops (intentionally or accidentally), the feed movement and the tool movement must be coordinated.

1.3.3. Risks due to falling or ejected objects

Precautions must be taken to prevent risks from falling or ejected objects.

1.3.4. Risks due to surfaces, edges or angles

Insofar as their purpose allows, accessible parts of the machinery must have no sharp edges, no sharp angles and no rough surfaces likely to cause injury.

1.3.5. Risks related to combined machinery

Where the machinery is intended to carry out several different operations with manual removal of the piece between each operation (combined machinery), it must be designed and constructed in such a way as to enable each element to be used separately without the other elements constituting a risk for exposed persons.

For this purpose, it must be possible to start and stop separately any elements that are not protected.

1.3.6. Risks related to variations in operating conditions

Where the machinery performs operations under different conditions of use, it must be designed and constructed in such a way that selection and adjustment of these conditions can be carried out safely and reliably.

1.3.7. Risks related to moving parts

The moving parts of machinery must be designed and constructed in such a way as to prevent risks of contact which could lead to accidents or must, where risks persist, be fitted with guards or protective devices.

All necessary steps must be taken to prevent accidental blockage of moving parts involved in the work. In cases where, despite the precautions taken, a blockage is likely to occur, the necessary specific protective devices and tools must, when appropriate, be provided to enable the equipment to be safely unblocked.

The instructions and, where possible, a sign on the machinery shall identify these specific protective devices and how they are to be used.
1.3.8. **Choice of protection against risks arising from moving parts**

Guards or protective devices designed to protect against risks arising from moving parts must be selected on the basis of the type of risk. The following guidelines must be used to help to make the choice.

1.3.8.1. **Moving transmission parts**

Guards designed to protect persons against the hazards generated by moving transmission parts must be:

— either fixed guards as referred to in section 1.4.2.1 below, or
— interlocking movable guards as referred to in section 1.4.2.2 below.

Interlocking movable guards should be used where frequent access is envisaged.

1.3.8.2. **Moving parts involved in the process**

Guards or protective devices designed to protect persons against the hazards generated by moving parts involved in the process must be:

— either fixed guards as referred to in section 1.4.2.1 below, or
— interlocking movable guards as referred to in section 1.4.2.2 below, or
— protective devices as referred to in section 1.4.3 below, or
— a combination of the above.

However, when certain moving parts directly involved in the process cannot be made completely inaccessible during operation owing to operations requiring operator intervention, such parts must be fitted with:

— fixed guards or interlocking movable guards preventing access to those sections of the parts that are not used in the work, and
— adjustable guards as referred to in section 1.4.2.3 below restricting access to those sections of the moving parts where access is necessary.

1.3.9. **Risks of uncontrolled movements**

When a part of the machinery has been stopped, any drift away from the stopping position, for whatever reason other than action on the control devices, must be prevented or must be such that it does not present a hazard.

1.4. **REQUIRED CHARACTERISTICS OF GUARDS AND PROTECTIVE DEVICES**

1.4.1. **General requirements**

Guards and protective devices must:

— be of robust construction,
— be securely held in place,
— not give rise to any additional hazard,
— not be easy to by-pass or render non-operational,
— be located at an adequate distance from the danger zone,
— cause minimum obstruction to the view of the production process, and
— enable essential work to be carried out on the installation and/or replacement of tools and for maintenance purposes by restricting access exclusively to the area where the work has to be done, if possible without the guard having to be removed or the protective device having to be disabled.

In addition, guards must, where possible, protect against the ejection or falling of materials or objects and against emissions generated by the machinery.

1.4.2. Special requirements for guards

1.4.2.1. Fixed guards

Fixed guards must be fixed by systems that can be opened or removed only with tools.

Their fixing systems must remain attached to the guards or to the machinery when the guards are removed.

Where possible, guards must be incapable of remaining in place without their fixings.

1.4.2.2. Interlocking movable guards

Interlocking movable guards must:
— as far as possible remain attached to the machinery when open,
— be designed and constructed in such a way that they can be adjusted only by means of an intentional action.

Interlocking movable guards must be associated with an interlocking device that:
— prevents the start of hazardous machinery functions until they are closed and
— gives a stop command whenever they are no longer closed.

Where it is possible for an operator to reach the danger zone before the risk due to the hazardous machinery functions has ceased, movable guards must be associated with a guard locking device in addition to an interlocking device that:
— prevents the start of hazardous machinery functions until the guard is closed and locked, and
— keeps the guard closed and locked until the risk of injury from the hazardous machinery functions has ceased.

Interlocking movable guards must be designed in such a way that the absence or failure of one of their components prevents starting or stops the hazardous machinery functions.

1.4.2.3. Adjustable guards restricting access

Adjustable guards restricting access to those areas of the moving parts strictly necessary for the work must be:
— adjustable manually or automatically, depending on the type of work involved, and
— readily adjustable without the use of tools.
1.4.3. Special requirements for protective devices

Protective devices must be designed and incorporated into the control system in such a way that:
— moving parts cannot start up while they are within the operator’s reach,
— persons cannot reach moving parts while the parts are moving, and
— the absence or failure of one of their components prevents starting or stops the moving parts.

Protective devices must be adjustable only by means of an intentional action.

1.5. RISKS DUE TO OTHER HAZARDS

1.5.1. Electricity supply

Where machinery has an electricity supply, it must be designed, constructed and equipped in such a way that all hazards of an electrical nature are or can be prevented.

The safety objectives set out in Directive 2006/95/EC shall apply to machinery. However, the obligations concerning conformity assessment and the placing on the market and/or putting into service of machinery with regard to electrical hazards are governed solely by the Directive.

1.5.2. Static electricity

Machinery must be designed and constructed to prevent or limit the build-up of potentially dangerous electrostatic charges and/or be fitted with a discharging system.

1.5.3. Energy supply other than electricity

Where machinery is powered by sources of energy other than electricity, it must be so designed, constructed and equipped as to avoid all potential risks associated with such sources of energy.

1.5.4. Errors of fitting

Errors likely to be made when fitting or refitting certain parts which could be a source of risk must be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information must be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.

Where necessary, the instructions must give further information on these risks.

Where a faulty connection can be the source of risk, incorrect connections must be made impossible by design or, failing this, by information given on the elements to be connected and, where appropriate, on the means of connection.

1.5.5. Extreme temperatures

Steps must be taken to eliminate any risk of injury arising from contact with or proximity to machinery parts or materials at high or very low temperatures.

The necessary steps must also be taken to avoid or protect against the risk of hot or very cold material being ejected.

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1.5.6. **Fire**

Machinery must be designed and constructed in such a way as to avoid any risk of fire or overheating posed by the machinery itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery.

1.5.7. **Explosion**

Machinery must be designed and constructed in such a way as to avoid any risk of explosion posed by the machinery itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery.

Machinery must comply, as far as the risk of explosion due to its use in a potentially explosive atmosphere is concerned, with the provisions of the specific Community directives.

1.5.8. **Noise**

Machinery must be designed and constructed in such a way that risks resulting from the emission of airborne noise are reduced to the lowest level, taking account of technical progress and the availability of means of reducing noise, in particular at source.

The level of noise emission may be assessed with reference to comparative emission data for similar machinery.

1.5.9. **Vibrations**

Machinery must be designed and constructed in such a way that risks resulting from vibrations produced by the machinery are reduced to the lowest level, taking account of technical progress and the availability of means of reducing vibration, in particular at source.

The level of vibration emission may be assessed with reference to comparative emission data for similar machinery.

1.5.10. **Radiation**

Undesirable radiation emissions from the machinery must be eliminated or be reduced to levels that do not have adverse effects on persons.

Any functional ionising radiation emissions must be limited to the lowest level which is sufficient for the proper functioning of the machinery during setting, operation and cleaning. Where a risk exists, the necessary protective measures must be taken.

Any functional non-ionising radiation emissions during setting, operation and cleaning must be limited to levels that do not have adverse effects on persons.

1.5.11. **External radiation**

Machinery must be designed and constructed in such a way that external radiation does not interfere with its operation.

1.5.12. **Laser radiation**

Where laser equipment is used, the following should be taken into account:

— laser equipment on machinery must be designed and constructed in such a way as to prevent any accidental radiation,

— laser equipment on machinery must be protected in such a way that effective radiation, radiation produced by reflection or diffusion and secondary radiation do not damage health,
— optical equipment for the observation or adjustment of laser equipment on machinery must be such that no health risk is created by laser radiation.

1.5.13. **Emissions of hazardous materials and substances**

Machinery must be designed and constructed in such a way that risks of inhalation, ingestion, contact with the skin, eyes and mucous membranes and penetration through the skin of hazardous materials and substances which it produces can be avoided.

Where a hazard cannot be eliminated, the machinery must be so equipped that hazardous materials and substances can be contained, evacuated, precipitated by water spraying, filtered or treated by another equally effective method.

Where the process is not totally enclosed during normal operation of the machinery, the devices for containment and/or evacuation must be situated in such a way as to have the maximum effect.

1.5.14. **Risk of being trapped in a machine**

Machinery must be designed, constructed or fitted with a means of preventing a person from being enclosed within it or, if that is impossible, with a means of summoning help.

1.5.15. **Risk of slipping, tripping or falling**

Parts of the machinery where persons are liable to move about or stand must be designed and constructed in such a way as to prevent persons slipping, tripping or falling on or off these parts.

Where appropriate, these parts must be fitted with handholds that are fixed relative to the user and that enable them to maintain their stability.

1.5.16. **Lightning**

Machinery in need of protection against the effects of lightning while being used must be fitted with a system for conducting the resultant electrical charge to earth.

1.6. **MAINTENANCE**

1.6.1. **Machinery maintenance**

Adjustment and maintenance points must be located outside danger zones. It must be possible to carry out adjustment, maintenance, repair, cleaning and servicing operations while machinery is at a standstill.

If one or more of the above conditions cannot be satisfied for technical reasons, measures must be taken to ensure that these operations can be carried out safely (see section 1.2.5 above).

In the case of automated machinery and, where necessary, other machinery, a connecting device for mounting diagnostic fault-finding equipment must be provided.

Automated machinery components which have to be changed frequently must be capable of being removed and replaced easily and safely. Access to the components must enable these tasks to be carried out with the necessary technical means in accordance with a specified operating method.

1.6.2. **Access to operating positions and servicing points**

Machinery must be designed and constructed in such a way as to allow access in safety to all areas where intervention is necessary during operation, adjustment and maintenance of the machinery.
1.6.3. Isolation of energy sources

Machinery must be fitted with means to isolate it from all energy sources. Such isolators must be clearly identified. They must be capable of being locked if reconnection could endanger persons. Isolators must also be capable of being locked where an operator is unable, from any of the points to which he has access, to check that the energy is still cut off.

In the case of machinery capable of being plugged into an electricity supply, removal of the plug is sufficient, provided that the operator can check from any of the points to which he has access that the plug remains removed.

After the energy is cut off, it must be possible to dissipate normally any energy remaining or stored in the circuits of the machinery without risk to persons.

As an exception to the requirement laid down in the previous paragraphs, certain circuits may remain connected to their energy sources in order, for example, to hold parts, to protect information, to light interiors, etc. In this case, special steps must be taken to ensure operator safety.

1.6.4. Operator intervention

Machinery must be so designed, constructed and equipped that the need for operator intervention is limited. If operator intervention cannot be avoided, it must be possible to carry it out easily and safely.

1.6.5. Cleaning of internal parts

The machinery must be designed and constructed in such a way that it is possible to clean internal parts which have contained dangerous substances or preparations without entering them; any necessary unblocking must also be possible from the outside. If it is impossible to avoid entering the machinery, it must be designed and constructed in such a way as to allow cleaning to take place safely.

1.7. INFORMATION

1.7.1. Information and warnings on the machinery

Information and warnings on the machinery should preferably be provided in the form of readily understandable symbols or pictograms. Any written or verbal information and warnings must be expressed in an official Community language or languages, which may be determined in accordance with the Treaty by the Member State in which the machinery is placed on the market and/or put into service and may be accompanied, on request, by versions in any other official Community language or languages understood by the operators.

1.7.1.1. Information and information devices

The information needed to control machinery must be provided in a form that is unambiguous and easily understood. It must not be excessive to the extent of overloading the operator.

Visual display units or any other interactive means of communication between the operator and the machine must be easily understood and easy to use.

1.7.1.2. Warning devices

Where the health and safety of persons may be endangered by a fault in the operation of unsupervised machinery, the machinery must be equipped in such a way as to give an appropriate acoustic or light signal as a warning.
Where machinery is equipped with warning devices these must be unambiguous and easily perceived. The operator must have facilities to check the operation of such warning devices at all times.

The requirements of the specific Community directives concerning colours and safety signals must be complied with.

1.7.2. Warning of residual risks

Where risks remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted, the necessary warnings, including warning devices, must be provided.

1.7.3. Marking of machinery

All machinery must be marked visibly, legibly and indelibly with the following minimum particulars:

— the business name and full address of the manufacturer and, where applicable, his authorised representative,

— designation of the machinery,

— the CE Marking (see Part 3 of this Schedule (Annex III)),

— designation of series or type,

— serial number, if any,

— the year of construction, that is the year in which the manufacturing process is completed.

It is prohibited to pre-date or post-date the machinery when affixing the CE marking.

Furthermore, machinery designed and constructed for use in a potentially explosive atmosphere must be marked accordingly.

Machinery must also bear full information relevant to its type and essential for safe use. Such information is subject to the requirements set out in section 1.7.1 above.

Where a machine part must be handled during use with lifting equipment, its mass must be indicated legibly, indelibly and unambiguously.

1.7.4. Instructions

All machinery must be accompanied by instructions in the official Community language or languages of the Member State in which it is placed on the market and/or put into service.

The instructions accompanying the machinery must be either “Original instructions” or a “Translation of the original instructions”, in which case the translation must be accompanied by the original instructions.

By way of exception, the maintenance instructions intended for use by specialised personnel mandated by the responsible person may be supplied in only one Community language which the specialised personnel understand.

The instructions must be drafted in accordance with the principles set out below.
1.7.4.1. General principles for the drafting of instructions

(a) The instructions must be drafted in one or more official Community languages. The words “Original instructions” must appear on the language version(s) verified by the responsible person.

(b) Where no “Original instructions” exist in the official language(s) of the country where the machinery is to be used, a translation into that/those language(s) must be provided by the responsible person or by the person bringing the machinery into the language area in question. The translations must bear the words “Translation of the original instructions”.

(c) The contents of the instructions must cover not only the intended use of the machinery but also take into account any reasonably foreseeable misuse thereof.

(d) In the case of machinery intended for use by non-professional operators, the wording and layout of the instructions for use must take into account the level of general education and acumen that can reasonably be expected from such operators.

1.7.4.2. Contents of the instructions

Each instruction manual must contain, where applicable, at least the following information:

(a) the business name and full address of the manufacturer and of his authorised representative;

(b) the designation of the machinery as marked on the machinery itself, except for the serial number (see section 1.7.3 above);

(c) the EC declaration of conformity, or a document setting out the contents of the EC declaration of conformity, showing the particulars of the machinery, not necessarily including the serial number and the signature;

(d) a general description of the machinery;

(e) the drawings, diagrams, descriptions and explanations necessary for the use, maintenance and repair of the machinery and for checking its correct functioning;

(f) a description of the workstation(s) likely to be occupied by operators;

(g) a description of the intended use of the machinery;

(h) warnings concerning ways in which the machinery must not be used that experience has shown might occur;

(i) assembly, installation and connection instructions, including drawings, diagrams and the means of attachment and the designation of the chassis or installation on which the machinery is to be mounted;

(j) instructions relating to installation and assembly for reducing noise or vibration;

(k) instructions for the putting into service and use of the machinery and, if necessary, instructions for the training of operators;

(l) information about the residual risks that remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted;

(m) instructions on the protective measures to be taken by the user, including, where appropriate, the personal protective equipment to be provided;

(n) the essential characteristics of tools which may be fitted to the machinery;
(o) the conditions in which the machinery meets the requirement of stability during use, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns;

(p) instructions with a view to ensuring that transport, handling and storage operations can be made safely, giving the mass of the machinery and of its various parts where these are regularly to be transported separately;

(q) the operating method to be followed in the event of accident or breakdown; if a blockage is likely to occur, the operating method to be followed so as to enable the equipment to be safely unblocked;

(r) the description of the adjustment and maintenance operations that should be carried out by the user and the preventive maintenance measures that should be observed;

(s) instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations;

(t) the specifications of the spare parts to be used, when these affect the health and safety of operators;

(u) the following information on airborne noise emissions:

— the A-weighted emission sound pressure level at workstations, where this exceeds 70 dB(A); where this level does not exceed 70 dB(A), this fact must be indicated,

— the peak C-weighted instantaneous sound pressure value at workstations, where this exceeds 63 Pa (130 dB in relation to 20 µPa),

— the A-weighted sound power level emitted by the machinery, where the A-weighted emission sound pressure level at workstations exceeds 80 dB(A).

These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced.

In the case of very large machinery, instead of the A-weighted sound power level, the A-weighted emission sound pressure levels at specified positions around the machinery may be indicated.

Where the harmonised standards are not applied, sound levels must be measured using the most appropriate method for the machinery. Whenever sound emission values are indicated the uncertainties surrounding these values must be specified. The operating conditions of the machinery during measurement and the measuring methods used must be described.

Where the workstation(s) are undefined or cannot be defined, A-weighted sound pressure levels must be measured at a distance of 1 metre from the surface of the machinery and at a height of 1.6 metres from the floor or access platform. The position and value of the maximum sound pressure must be indicated.

Where specific Community directives lay down other requirements for the measurement of sound pressure levels or sound power levels, the provisions of those Community directives must be applied and the corresponding provisions of this section shall not apply;

(v) where machinery is likely to emit non-ionising radiation which may cause harm to persons, in particular persons with active or non-active implantable medical devices, information concerning the radiation emitted for the operator and exposed persons.
1.7.4.3. Sales literature

Sales literature describing the machinery must not contradict the instructions as regards health and safety aspects. Sales literature describing the performance characteristics of machinery must contain the same information on emissions as is contained in the instructions.

2. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR CERTAIN CATEGORIES OF MACHINERY

Foodstuffs machinery, machinery for cosmetics or pharmaceutical products, hand-held and/or hand-guided machinery, portable fixing and other impact machinery, machinery for working wood and material with similar physical characteristics must meet all the essential health and safety requirements described in this section (see point 4 of the General Principles at the start of this Annex).

2.1. FOODSTUFFS MACHINERY AND MACHINERY FOR COSMETICS OR PHARMACEUTICAL PRODUCTS

2.1.1. General

Machinery intended for use with foodstuffs or with cosmetics or pharmaceutical products must be designed and constructed in such a way as to avoid any risk of infection, sickness or contagion.

The following requirements must be observed:

(a) materials in contact with, or intended to come into contact with, foodstuffs or cosmetics or pharmaceutical products must satisfy the conditions set down in the relevant Directives. The machinery must be designed and constructed in such a way that these materials can be cleaned before each use. Where this is not possible disposable parts must be used;

(b) all surfaces in contact with foodstuffs or cosmetics or pharmaceutical products, other than surfaces of disposable parts, must:

— be smooth and have neither ridges nor crevices which could harbour organic materials. The same applies to their joinings,

— be designed and constructed in such a way as to reduce the projections, edges and recesses of assemblies to a minimum,

— be easily cleaned and disinfected, where necessary after removing easily dismantled parts; the inside surfaces must have curves with a radius sufficient to allow thorough cleaning;

(c) it must be possible for liquids, gases and aerosols deriving from foodstuffs, cosmetics or pharmaceutical products as well as from cleaning, disinfecting and rinsing fluids to be completely discharged from the machinery (if possible, in a “cleaning” position);

(d) machinery must be designed and constructed in such a way as to prevent any substances or living creatures, in particular insects, from entering, or any organic matter from accumulating in, areas that cannot be cleaned;

(e) machinery must be designed and constructed in such a way that no ancillary substances hazardous to health, including the lubricants used, can come into contact with foodstuffs, cosmetics or pharmaceutical products. Where necessary, machinery must be designed and constructed in such a way that continuing compliance with this requirement can be checked.
2.1.2. Instructions

The instructions for foodstuffs machinery and machinery for use with cosmetics or pharmaceutical products must indicate recommended products and methods for cleaning, disinfecting and rinsing, not only for easily accessible areas but also for areas to which access is impossible or inadvisable.

2.2. PORTABLE HAND-HELD AND/OR HAND-GUIDED MACHINERY

2.2.1. General

Portable hand-held and/or hand-guided machinery must:

— depending on the type of machinery, have a supporting surface of sufficient size and have a sufficient number of handles and supports of an appropriate size, arranged in such a way as to ensure the stability of the machinery under the intended operating conditions,

— except where technically impossible, or where there is an independent control device, in the case of handles which cannot be released in complete safety, be fitted with manual start and stop control devices arranged in such a way that the operator can operate them without releasing the handles,

— present no risks of accidental starting and/or continued operation after the operator has released the handles. Equivalent steps must be taken if this requirement is not technically feasible,

— permit, where necessary, visual observation of the danger zone and of the action of the tool with the material being processed.

The handles of portable machinery must be designed and constructed in such a way as to make starting and stopping straightforward.

2.2.1.1. Instructions

The instructions must give the following information concerning vibrations transmitted by portable hand-held and hand-guided machinery:

— the vibration total value to which the hand-arm system is subjected, if it exceeds 2.5 m/s². Where this value does not exceed 2.5 m/s², this must be mentioned,

— the uncertainty of measurement.

These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced.

If harmonised standards are not applied, the vibration data must be measured using the most appropriate measurement code for the machinery.

The operating conditions during measurement and the methods used for measurement, or the reference of the harmonised standard applied, must be specified.

2.2.2. Portable fixing and other impact machinery

2.2.2.1. General

Portable fixing and other impact machinery must be designed and constructed in such a way that:

— energy is transmitted to the impacted element by the intermediary component that does not leave the device,
— an enabling device prevents impact unless the machinery is positioned correctly with adequate pressure on the base material,

— involuntary triggering is prevented; where necessary, an appropriate sequence of actions on the enabling device and the control device must be required to trigger an impact,

— accidental triggering is prevented during handling or in case of shock,

— loading and unloading operations can be carried out easily and safely.

Where necessary, it must be possible to fit the device with splinter guard(s) and the appropriate guard(s) must be provided by the manufacturer of the machinery.

2.2.2.2. Instructions

The instructions must give the necessary information regarding:

— the accessories and interchangeable equipment that can be used with the machinery,

— the suitable fixing or other impacted elements to be used with the machinery,

— where appropriate, the suitable cartridges to be used.

2.3. MACHINERY FOR WORKING WOOD AND MATERIAL WITH SIMILAR PHYSICAL CHARACTERISTICS

Machinery for working wood and materials with similar physical characteristics must comply with the following requirements:

(a) the machinery must be designed, constructed or equipped in such a way that the piece being machined can be placed and guided in safety; where the piece is hand-held on a work-bench, the latter must be sufficiently stable during the work and must not impede the movement of the piece;

(b) where the machinery is likely to be used in conditions involving the risk of ejection of workpieces or parts of them, it must be designed, constructed, or equipped in such a way as to prevent such ejection, or, if this is not possible, so that the ejection does not engender risks for the operator and/or exposed persons;

(c) the machinery must be equipped with an automatic brake that stops the tool in a sufficiently short time if there is a risk of contact with the tool whilst it runs down;

(d) where the tool is incorporated into a non-fully automated machine, the latter must be designed and constructed in such a way as to eliminate or reduce the risk of accidental injury.

3. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS DUE TO THE MOBILITY OF MACHINERY

Machinery presenting hazards due to its mobility must meet all the essential health and safety requirements described in this section (see point 4 of the General Principles at the start of this Annex).

3.1. GENERAL

3.1.1. Definitions

(a) “Machinery presenting hazards due to its mobility” means

— machinery the operation of which requires either mobility while working, or continuous or semi-continuous movement between a succession of fixed working locations, or
— machinery which is operated without being moved, but which may be equipped in such a way as to enable it to be moved more easily from one place to another.

(b) “Driver” means an operator responsible for the movement of a machine. The driver may be transported by the machinery or may be on foot, accompanying the machinery, or may guide the machinery by remote control.

3.2. WORK POSITIONS

3.2.1. **Driving position**

Visibility from the driving position must be such that the driver can, in complete safety for himself and the exposed persons, operate the machinery and its tools in their foreseeable conditions of use. Where necessary, appropriate devices must be provided to remedy hazards due to inadequate direct vision.

Machinery on which the driver is transported must be designed and constructed in such a way that, from the driving positions, there is no risk to the driver from inadvertent contact with the wheels and tracks.

The driving position of ride-on drivers must be designed and constructed in such a way that a driver’s cab may be fitted, provided this does not increase the risk and there is room for it. The cab must incorporate a place for the instructions needed for the driver.

3.2.2. **Seating**

Where there is a risk that operators or other persons transported by the machinery may be crushed between parts of the machinery and the ground should the machinery roll or tip over, in particular for machinery equipped with a protective structure referred to in section 3.4.3 or 3.4.4 below, their seats must be designed or equipped with a restraint system so as to keep the persons in their seats, without restricting movements necessary for operations or movements relative to the structure caused by the suspension of the seats. Such restraint systems should not be fitted if they increase the risk.

3.2.3. **Positions for other persons**

If the conditions of use provide that persons other than the driver may occasionally or regularly be transported by the machinery or work on it, appropriate positions must be provided which enable them to be transported or to work on it without risk.

The second and third paragraphs of section 3.2.1 above also apply to the places provided for persons other than the driver.

3.3. CONTROL SYSTEMS

If necessary, steps must be taken to prevent unauthorised use of controls.

In the case of remote controls, each control unit must clearly identify the machinery to be controlled from that unit.

The remote control system must be designed and constructed in such a way as to affect only:

— the machinery in question,

— the functions in question.

Remote controlled machinery must be designed and constructed in such a way that it will respond only to signals from the intended control units.
3.3.1. **Control devices**

The driver must be able to actuate all control devices required to operate the machinery from the driving position, except for functions which can be safely actuated only by using control devices located elsewhere. These functions include, in particular, those for which operators other than the driver are responsible or for which the driver has to leave the driving position in order to control them safely.

Where there are pedals, they must be so designed, constructed and fitted as to allow safe operation by the driver with the minimum risk of incorrect operation. They must have a slip—resistant surface and be easy to clean.

Where their operation can lead to hazards, notably dangerous movements, the control devices, except for those with preset positions, must return to the neutral position as soon as they are released by the operator.

In the case of wheeled machinery, the steering system must be designed and constructed in such a way as to reduce the force of sudden movements of the steering wheel or the steering lever caused by shocks to the guide wheels.

Any control that locks the differential must be so designed and arranged that it allows the differential to be unlocked when the machinery is moving.

The sixth paragraph of section 1.2.2 above, concerning acoustic and/or visual warning signals, applies only in the case of reversing.

3.3.2. **Starting/moving**

All travel movements of self-propelled machinery with a ride-on driver must be possible only if the driver is at the controls.

Where, for operating purposes, machinery is fitted with devices which exceed its normal clearance zone (e.g. stabilisers, jib, etc.), the driver must be provided with the means of checking easily, before moving the machinery, that such devices are in a particular position which allows safe movement.

This also applies to all other parts which, to allow safe movement, have to be in particular positions, locked if necessary.

Where it does not give rise to other risks, movement of the machinery must depend on safe positioning of the aforementioned parts.

It must not be possible for unintentional movement of the machinery to occur while the engine is being started.

3.3.3. **Travelling function**

Without prejudice to road traffic regulations, self-propelled machinery and its trailers must meet the requirements for slowing down, stopping, braking and immobilisation so as to ensure safety under all the operating, load, speed, ground and gradient conditions allowed for.

The driver must be able to slow down and stop self-propelled machinery by means of a main device. Where safety so requires, in the event of a failure of the main device, or in the absence of the energy supply needed to actuate the main device, an emergency device with a fully independent and easily accessible control device must be provided for slowing down and stopping.

Where safety so requires, a parking device must be provided to render stationary machinery immobile. This device may be combined with one of the devices referred to in the second paragraph, provided that it is purely mechanical.
Remote—controlled machinery must be equipped with devices for stopping operation automatically and immediately and for preventing potentially dangerous operation in the following situations:

— if the driver loses control,
— if it receives a stop signal,
— if a fault is detected in a safety-related part of the system,
— if no validation signal is detected within a specified time.

Section 1.2.4 above does not apply to the travelling function.

3.3.4. Movement of pedestrian—controlled machinery

Movement of pedestrian-controlled self-propelled machinery must be possible only through sustained action on the relevant control device by the driver. In particular, it must not be possible for movement to occur while the engine is being started.

The control systems for pedestrian-controlled machinery must be designed in such a way as to minimise the risks arising from inadvertent movement of the machine towards the driver, in particular:

— crushing,
— injury from rotating tools.

The speed of travel of the machinery must be compatible with the pace of a driver on foot.

In the case of machinery on which a rotary tool may be fitted, it must not be possible to actuate the tool when the reverse control is engaged, except where the movement of the machinery results from movement of the tool. In the latter case, the reversing speed must be such that it does not endanger the driver.

3.3.5. Control circuit failure

A failure in the power supply to the power-assisted steering, where fitted, must not prevent machinery from being steered during the time required to stop it.

3.4. PROTECTION AGAINST MECHANICAL HAZARDS

3.4.1. Uncontrolled movements

Machinery must be designed, constructed and where appropriate placed on its mobile support in such a way as to ensure that, when moved, uncontrolled oscillations of its centre of gravity do not affect its stability or exert excessive strain on its structure.

3.4.2. Moving transmission parts

By way of exception to section 1.3.8.1 above, in the case of engines, moveable guards preventing access to the moving parts in the engine compartment need not have interlocking devices if they have to be opened either by the use of a tool or key or by a control located in the driving position, providing the latter is in a fully enclosed cab with a lock to prevent unauthorised access.
3.4.3. **Roll-over and tip-over**

Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk of rolling or tipping over, the machinery must be fitted with an appropriate protective structure, unless this increases the risk.

This structure must be such that in the event of rolling or tipping over it affords the ride-on person(s) an adequate deflection-limiting volume.

In order to verify that the structure complies with the requirement laid down in the second paragraph, the responsible person must, for each type of structure concerned, perform appropriate tests or have such tests performed.

3.4.4. **Falling objects**

Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk due to falling objects or material, the machinery must be designed and constructed in such a way as to take account of this risk and fitted, if its size allows, with an appropriate protective structure.

This structure must be such that, in the event of falling objects or material, it guarantees the ride-on person(s) an adequate deflection-limiting volume.

In order to verify that the structure complies with the requirement laid down in the second paragraph, the responsible person must, for each type of structure concerned, perform appropriate tests or have such tests performed.

3.4.5. **Means of access**

Handholds and steps must be designed, constructed and arranged in such a way that the operators use them instinctively and do not use the control devices to assist access.

3.4.6. **Towing devices**

All machinery used to tow or to be towed must be fitted with towing or coupling devices designed, constructed and arranged in such a way as to ensure easy and secure connection and disconnection and to prevent accidental disconnection during use.

Insofar as the tow bar load so requires, such machinery must be equipped with a support with a bearing surface suited to the load and the ground.

3.4.7. **Transmission of power between self-propelled machinery (or tractor) and recipient machinery**

Removable mechanical transmission devices linking self-propelled machinery (or a tractor) to the first fixed bearing of recipient machinery must be designed and constructed in such a way that any part that moves during operation is protected over its whole length.

On the side of the self-propelled machinery (or tractor), the power take-off to which the removable mechanical transmission device is attached must be protected either by a guard fixed and linked to the self-propelled machinery (or tractor) or by any other device offering equivalent protection.

It must be possible to open this guard for access to the removable transmission device. Once it is in place, there must be enough room to prevent the drive shaft damaging the guard when the machinery (or the tractor) is moving.

On the recipient machinery side, the input shaft must be enclosed in a protective casing fixed to the machinery.
Torque limiters or freewheels may be fitted to universal joint transmissions only on the side adjoining the driven machinery. The removable mechanical transmission device must be marked accordingly.

All recipient machinery, the operation of which requires a removable mechanical transmission device to connect it to self-propelled machinery (or a tractor), must have a system for attaching the removable mechanical transmission device so that, when the machinery is uncoupled, the removable mechanical transmission device and its guard are not damaged by contact with the ground or part of the machinery.

The outside parts of the guard must be so designed, constructed and arranged that they cannot turn with the removable mechanical transmission device. The guard must cover the transmission to the ends of the inner jaws in the case of simple universal joints and at least to the centre of the outer joint or joints in the case of wide-angle universal joints.

If means of access to working positions are provided near to the removable mechanical transmission device, they must be designed and constructed in such a way that the shaft guards cannot be used as steps, unless designed and constructed for that purpose.

3.5. PROTECTION AGAINST OTHER HAZARDS

3.5.1. Batteries

The battery housing must be designed and constructed in such a way as to prevent the electrolyte being ejected on to the operator in the event of rollover or tipover and to avoid the accumulation of vapours in places occupied by operators.

Machinery must be designed and constructed in such a way that the battery can be disconnected with the aid of an easily accessible device provided for that purpose.

3.5.2. Fire

Depending on the hazards anticipated by the manufacturer, machinery must, where its size permits:

— either allow easily accessible fire extinguishers to be fitted, or

— be provided with built-in extinguisher systems.

3.5.3. Emissions of hazardous substances

The second and third paragraphs of section 1.5.13 above do not apply where the main function of the machinery is the spraying of products. However, the operator must be protected against the risk of exposure to such hazardous emissions.

3.6. INFORMATION AND INDICATIONS

3.6.1. Signs, signals and warnings

All machinery must have signs and/or instruction plates concerning use, adjustment and maintenance, wherever necessary, so as to ensure the health and safety of persons. They must be chosen, designed and constructed in such a way as to be clearly visible and indelible.

Without prejudice to the provisions of road traffic regulations, machinery with a ride-on driver must have the following equipment:

— an acoustic warning device to alert persons,
— a system of light signals relevant to the intended conditions of use; the latter requirement does not apply to machinery intended solely for underground working and having no electrical power,

— where necessary, there must be an appropriate connection between a trailer and the machinery for the operation of signals.

Remote-controlled machinery which, under normal conditions of use, exposes persons to the risk of impact or crushing must be fitted with appropriate means to signal its movements or with means to protect persons against such risks. The same applies to machinery which involves, when in use, the constant repetition of a forward and backward movement on a single axis where the area to the rear of the machine is not directly visible to the driver.

Machinery must be constructed in such a way that the warning and signalling devices cannot be disabled unintentionally. Where it is essential for safety, such devices must be provided with the means to check that they are in good working order and their failure must be made apparent to the operator.

Where the movement of machinery or its tools is particularly hazardous, signs on the machinery must be provided to warn against approaching the machinery while it is working; the signs must be legible at a sufficient distance to ensure the safety of persons who have to be in the vicinity.

3.6.2. Marking

The following must be shown legibly and indelibly on all machinery:

— nominal power expressed in kilowatts (kW),

— mass of the most usual configuration, in kilograms (kg);

and, where appropriate:

— maximum drawbar pull provided for at the coupling hook, in Newtons (N),

— maximum vertical load provided for on the coupling hook, in Newtons (N).

3.6.3. Instructions

3.6.3.1. Vibrations

The instructions must give the following information concerning vibrations transmitted by the machinery to the hand-arm system or to the whole body:

— the vibration total value to which the hand-arm system is subjected, if it exceeds 2.5 m/s². Where this value does not exceed 2.5 m/s², this must be mentioned,

— the highest root mean square value of weighted acceleration to which the whole body is subjected, if it exceeds 0.5 m/s². Where this value does not exceed 0.5 m/s², this must be mentioned,

— the uncertainty of measurement.

These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced.

Where harmonised standards are not applied, the vibration must be measured using the most appropriate measurement code for the machinery concerned.

The operating conditions during measurement and the measurement codes used must be described.
3.6.3.2. Multiple uses

The instructions for machinery allowing several uses depending on the equipment used and the instructions for the interchangeable equipment must contain the information necessary for safe assembly and use of the basic machinery and the interchangeable equipment that can be fitted.

4. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS DUE TO LIFTING OPERATIONS

Machinery presenting hazards due to lifting operations must meet all the relevant essential health and safety requirements described in this section (see point 4 of the General Principles at the start of this Annex).

4.1. GENERAL

4.1.1. Definitions

(a) “Lifting operation” means a movement of unit loads consisting of goods and/or persons necessitating, at a given moment, a change of level.

(b) “Guided load” means a load where the total movement is made along rigid or flexible guides whose position is determined by fixed points.

(c) “Working coefficient” means the arithmetic ratio between the load guaranteed by the responsible person up to which a component is able to hold it and the maximum working load marked on the component.

(d) “Test coefficient” means the arithmetic ratio between the load used to carry out the static or dynamic tests on lifting machinery or a lifting accessory and the maximum working load marked on the lifting machinery or lifting accessory.

(e) “Static test” means the test during which lifting machinery or a lifting accessory is first inspected and subjected to a force corresponding to the maximum working load multiplied by the appropriate static test coefficient and then re-inspected once the said load has been released to ensure that no damage has occurred.

(f) “Dynamic test” means the test during which lifting machinery is operated in all its possible configurations at the maximum working load multiplied by the appropriate dynamic test coefficient with account being taken of the dynamic behaviour of the lifting machinery in order to check that it functions properly.

(g) “Carrier” means a part of the machinery on or in which persons and/or goods are supported in order to be lifted.

4.1.2. Protection against mechanical hazards

4.1.2.1. Risks due to lack of stability

Machinery must be designed and constructed in such a way that the stability required by section 1.3.1 above is maintained both in service and out of service, including all stages of transportation, assembly and dismantling, during foreseeable component failures and also during the tests carried out in accordance with the instruction handbook. To that end, the responsible person must use the appropriate verification methods.

4.1.2.2. Machinery running on guide rails and rail tracks

Machinery must be provided with devices which act on the guide rails or tracks to prevent derailment.
If, despite such devices, there remains a risk of derailment or of failure of a rail or of a running component, devices must be provided which prevent the equipment, component or load from falling or the machinery from overturning.

4.1.2.3. **Mechanical strength**

Machinery, lifting accessories and their components must be capable of withstanding the stresses to which they are subjected, both in and, where applicable, out of use, under the installation and operating conditions provided for and in all relevant configurations, with due regard, where appropriate, to the effects of atmospheric factors and forces exerted by persons. This requirement must also be satisfied during transport, assembly and dismantling.

Machinery and lifting accessories must be designed and constructed in such a way as to prevent failure from fatigue and wear, taking due account of their intended use.

The materials used must be chosen on the basis of the intended working environments, with particular regard to corrosion, abrasion, impacts, extreme temperatures, fatigue, brittleness and ageing.

Machinery and lifting accessories must be designed and constructed in such a way as to withstand the overload in the static tests without permanent deformation or patent defect. Strength calculations must take account of the value of the static test coefficient chosen to guarantee an adequate level of safety. That coefficient has, as a general rule, the following values:

(a) manually-operated machinery and lifting accessories: 1.5;

(b) other machinery: 1.25.

Machinery must be designed and constructed in such a way as to undergo, without failure, the dynamic tests carried out using the maximum working load multiplied by the dynamic test coefficient. This dynamic test coefficient is chosen so as to guarantee an adequate level of safety: the coefficient is, as a general rule, equal to 1.1. As a general rule, the tests will be performed at the nominal speeds provided for. Should the control circuit of the machinery allow for a number of simultaneous movements, the tests must be carried out under the least favourable conditions, as a general rule by combining the movements concerned.

4.1.2.4. **Pulleys, drums, wheels, ropes and chains**

Pulleys, drums and wheels must have a diameter commensurate with the size of the ropes or chains with which they can be fitted.

Drums and wheels must be designed, constructed and installed in such a way that the ropes or chains with which they are equipped can be wound without coming off.

Ropes used directly for lifting or supporting the load must not include any splicing other than at their ends. Splicings are, however, tolerated in installations which are intended by design to be modified regularly according to needs of use.

Complete ropes and their endings must have a working coefficient chosen in such a way as to guarantee an adequate level of safety. As a general rule, this coefficient is equal to 5.

Lifting chains must have a working coefficient chosen in such a way as to guarantee an adequate level of safety. As a general rule, this coefficient is equal to 4.

In order to verify that an adequate working coefficient has been attained, the responsible person must, for each type of chain and rope used directly for lifting the load and for the rope ends, perform the appropriate tests or have such tests performed.
4.1.2.5. Lifting accessories and their components

Lifting accessories and their components must be sized with due regard to fatigue and ageing processes for a number of operating cycles consistent with their expected life-span as specified in the operating conditions for a given application.

Moreover:

(a) the working coefficient of wire-rope/rope-end combinations must be chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 5. Ropes must not comprise any splices or loops other than at their ends;

(b) where chains with welded links are used, they must be of the short-link type. The working coefficient of chains must be chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 4;

(c) the working coefficient for textile ropes or slings is dependent on the material, method of manufacture, dimensions and use. This coefficient must be chosen in such a way as to guarantee an adequate level of safety; it is, as a general rule, equal to 7, provided the materials used are shown to be of very good quality and the method of manufacture is appropriate to the intended use. Should this not be the case, the coefficient is, as a general rule, set at a higher level in order to secure an equivalent level of safety. Textile ropes and slings must not include any knots, connections or splicing other than at the ends of the sling, except in the case of an endless sling;

(d) all metallic components making up, or used with, a sling must have a working coefficient chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 4;

(e) the maximum working load of a multilegged sling is determined on the basis of the working coefficient of the weakest leg, the number of legs and a reduction factor which depends on the slinging configuration;

(f) in order to verify that an adequate working coefficient has been attained, the responsible person must, for each type of component referred to in (a), (b), (c) and (d), perform the appropriate tests or have such tests performed.

4.1.2.6. Control of movements

Devices for controlling movements must act in such a way that the machinery on which they are installed is kept safe.

(a) Machinery must be designed and constructed or fitted with devices in such a way that the amplitude of movement of its components is kept within the specified limits. The operation of such devices must, where appropriate, be preceded by a warning.

(b) Where several fixed or rail-mounted machines can be manoeuvred simultaneously in the same place, with risks of collision, such machinery must be designed and constructed in such a way as to make it possible to fit systems enabling these risks to be avoided.

(c) Machinery must be designed and constructed in such a way that the loads cannot creep dangerously or fall freely and unexpectedly, even in the event of partial or total failure of the power supply or when the operator stops operating the machine.

(d) It must not be possible, under normal operating conditions, to lower the load solely by friction brake, except in the case of machinery whose function requires it to operate in that way.

(e) Holding devices must be designed and constructed in such a way that inadvertent dropping of the loads is avoided.
4.1.2.7. **Movements of loads during handling**

The operating position of machinery must be located in such a way as to ensure the widest possible view of trajectories of the moving parts, in order to avoid possible collisions with persons, equipment or other machinery which might be manoeuvring at the same time and liable to constitute a hazard.

Machinery with guided loads must be designed and constructed in such a way as to prevent persons from being injured by movement of the load, the carrier or the counterweights, if any.

4.1.2.8. **Machinery serving fixed landings**

4.1.2.8.1. **Movements of the carrier**

The movement of the carrier of machinery serving fixed landings must be rigidly guided to and at the landings. Scissor systems are also regarded as rigid guidance.

4.1.2.8.2. **Access to the carrier**

Where persons have access to the carrier, the machinery must be designed and constructed in such a way as to ensure that the carrier remains stationary during access, in particular while it is being loaded or unloaded.

The machinery must be designed and constructed in such a way as to ensure that the difference in level between the carrier and the landing being served does not create a risk of tripping.

4.1.2.8.3. **Risks due to contact with the moving carrier**

Where necessary in order to fulfil the requirement expressed in the second paragraph of section 4.1.2.7 above, the travel zone must be rendered inaccessible during normal operation.

When, during inspection or maintenance, there is a risk that persons situated under or above the carrier may be crushed between the carrier and any fixed parts, sufficient free space must be provided either by means of physical refuges or by means of mechanical devices blocking the movement of the carrier.

4.1.2.8.4. **Risk due to the load falling off the carrier**

Where there is a risk due to the load falling off the carrier, the machinery must be designed and constructed in such a way as to prevent this risk.

4.1.2.8.5. **Landings**

Risks due to contact of persons at landings with the moving carrier or other moving parts must be prevented.

Where there is a risk due to persons falling into the travel zone when the carrier is not present at the landings, guards must be fitted in order to prevent this risk. Such guards must not open in the direction of the travel zone. They must be fitted with an interlocking device controlled by the position of the carrier that prevents:

— hazardous movements of the carrier until the guards are closed and locked,
— hazardous opening of a guard until the carrier has stopped at the corresponding landing.

4.1.3. **Fitness for purpose**

When lifting machinery or lifting accessories are placed on the market or are first put into service, the responsible person must ensure, by taking appropriate measures or having them taken, that the
machinery or the lifting accessories which are ready for use – whether manually or power-operated – can fulfil their specified functions safely.

The static and dynamic tests referred to in section 4.1.2.3 above must be performed on all lifting machinery ready to be put into service.

Where the machinery cannot be assembled in the manufacturer’s premises or in the premises of his authorised representative, the appropriate measures must be taken at the place of use. Otherwise, the measures may be taken either in the manufacturer’s premises or at the place of use.

4.2. REQUIREMENTS FOR MACHINERY WHOSE POWER SOURCE IS OTHER THAN MANUAL EFFORT

4.2.1. Control of movements

Hold-to-run control devices must be used to control the movements of the machinery or its equipment. However, for partial or complete movements in which there is no risk of the load or the machinery colliding, the said devices may be replaced by control devices authorising automatic stops at pre-selected positions without the operator holding a hold-to-run control device.

4.2.2. Loading control

Machinery with a maximum working load of not less than 1000 kilograms or an overturning moment of not less than 40000 Nm must be fitted with devices to warn the driver and prevent dangerous movements in the event:

— of overloading, either as a result of the maximum working load or the maximum working moment due to the load being exceeded, or

— of the overturning moment being exceeded.

4.2.3. Installations guided by ropes

Rope carriers, tractors or tractor carriers must be held by counterweights or by a device allowing permanent control of the tension.

4.3. INFORMATION AND MARKINGS

4.3.1. Chains, ropes and webbing

Each length of lifting chain, rope or webbing not forming part of an assembly must bear a mark or, where this is not possible, a plate or irremovable ring bearing the name and address of the responsible person and the identifying reference of the relevant certificate.

The certificate mentioned above must show at least the following information:

(a) the name and address of the manufacturer and, if appropriate, his authorised representative;

(b) a description of the chain or rope which includes:

— its nominal size,
— its construction,
— the material from which it is made, and
— any special metallurgical treatment applied to the material;

(c) the test method used;
(d) the maximum load to which the chain or rope should be subjected in service. A range of values may be given on the basis of the intended applications.

4.3.2. **Lifting accessories**

Lifting accessories must show the following particulars:

— identification of the material where this information is needed for safe use,

— the maximum working load.

In the case of lifting accessories on which marking is physically impossible, the particulars referred to in the first paragraph must be displayed on a plate or other equivalent means and securely affixed to the accessory.

The particulars must be legible and located in a place where they are not liable to disappear as a result of wear or jeopardise the strength of the accessory.

4.3.3. **Lifting machinery**

The maximum working load must be prominently marked on the machinery. This marking must be legible, indelible and in an un-coded form.

Where the maximum working load depends on the configuration of the machinery, each operating position must be provided with a load plate indicating, preferably in diagrammatic form or by means of tables, the working load permitted for each configuration.

Machinery intended for lifting goods only, equipped with a carrier which allows access to persons, must bear a clear and indelible warning prohibiting the lifting of persons. This warning must be visible at each place where access is possible.

4.4. **INSTRUCTIONS**

4.4.1. **Lifting accessories**

Each lifting accessory or each commercially indivisible batch of lifting accessories must be accompanied by instructions setting out at least the following particulars:

(a) the intended use;

(b) the limits of use (particularly for lifting accessories such as magnetic or vacuum pads which do not fully comply with section 4.1.2.6(e) above);

(c) instructions for assembly, use and maintenance;

(d) the static test coefficient used.

4.4.2. **Lifting machinery**

Lifting machinery must be accompanied by instructions containing information on:

(a) the technical characteristics of the machinery, and in particular:

— the maximum working load and, where appropriate, a copy of the load plate or load table described in the second paragraph of section 4.3.3 above,

— the reactions at the supports or anchors and, where appropriate, characteristics of the tracks,

— where appropriate, the definition and the means of installation of the ballast;
(b) the contents of the logbook, if the latter is not supplied with the machinery;

(c) advice for use, particularly to offset the lack of direct vision of the load by the operator;

(d) where appropriate, a test report detailing the static and dynamic tests carried out by or for the responsible person;

(e) for machinery which is not assembled on the premises of the manufacturer in the form in which it is to be used, the necessary instructions for performing the measures referred to in section 4.1.3 above before it is first put into service.

5. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY INTENDED FOR UNDERGROUND WORK

Machinery intended for underground work must meet all the essential health and safety requirements described in this section (see point 4 of the General Principles at the start of this Annex).

5.1. RISKS DUE TO LACK OF STABILITY

Powered roof supports must be designed and constructed in such a way as to maintain a given direction when moving and not slip before and while they come under load and after the load has been removed. They must be equipped with anchorages for the top plates of the individual hydraulic props.

5.2. MOVEMENT

Powered roof supports must allow for unhindered movement of persons.

5.3. CONTROL DEVICES

The accelerator and brake controls for movement of machinery running on rails must be hand-operated. However, enabling devices may be foot-operated.

The control devices of powered roof supports must be designed and positioned in such a way that, during displacement operations, operators are sheltered by a support in place. The control devices must be protected against any accidental release.

5.4. STOPPING

Self-propelled machinery running on rails for use in underground work must be equipped with an enabling device acting on the circuit controlling the movement of the machinery such that movement is stopped if the driver is no longer in control of the movement.

5.5. FIRE

The second indent of section 3.5.2 above is mandatory in respect of machinery which comprises highly flammable parts.

The braking system of machinery intended for use in underground workings must be designed and constructed in such a way that it does not produce sparks or cause fires.

Machinery with internal combustion engines for use in underground workings must be fitted only with engines using fuel with a low vaporising pressure and which exclude any spark of electrical origin.

5.6. EXHAUST EMISSIONS

Exhaust emissions from internal combustion engines must not be discharged upwards.
6. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY PRESENTING PARTICULAR HAZARDS DUE TO THE LIFTING OF PERSONS

Machinery presenting hazards due to the lifting of persons must meet all the relevant essential health and safety requirements described in this section (see point 4 of the General Principles at the start of this Annex).

6.1. GENERAL

6.1.1. Mechanical strength

The carrier, including any trapdoors, must be designed and constructed in such a way as to offer the space and strength corresponding to the maximum number of persons permitted on the carrier and the maximum working load.

The working coefficients for components set out in sections 4.1.2.4 and 4.1.2.5 above are inadequate for machinery intended for the lifting of persons and must, as a general rule, be doubled. Machinery intended for lifting persons or persons and goods must be fitted with a suspension or supporting system for the carrier designed and constructed in such a way as to ensure an adequate overall level of safety and to prevent the risk of the carrier falling.

If ropes or chains are used to suspend the carrier, as a general rule, at least two independent ropes or chains are required, each with its own anchorage.

6.1.2. Loading control for machinery moved by power other than human strength

The requirements of section 4.2.2 above apply regardless of the maximum working load and overturning moment, unless the manufacturer can demonstrate that there is no risk of overloading or overturning.

6.2. CONTROL DEVICES

Where safety requirements do not impose other solutions, the carrier must, as a general rule, be designed and constructed in such a way that persons in the carrier have means of controlling upward and downward movements and, if appropriate, other movements of the carrier.

In operation, those control devices must override any other devices controlling the same movement with the exception of emergency stop devices.

The control devices for these movements must be of the hold-to-run type except where the carrier itself is completely enclosed.

6.3. RISKS TO PERSONS IN OR ON THE CARRIER

6.3.1. Risks due to movements of the carrier

Machinery for lifting persons must be designed, constructed or equipped in such a way that the acceleration or deceleration of the carrier does not engender risks for persons.

6.3.2. Risk of persons falling from the carrier

The carrier must not tilt to an extent which creates a risk of the occupants falling, including when the machinery and carrier are moving.

Where the carrier is designed as a work station, provision must be made to ensure stability and to prevent hazardous movements.
If the measures referred to in section 1.5.15 above are not adequate, carriers must be fitted with a sufficient number of suitable anchorage points for the number of persons permitted on the carrier. The anchorage points must be strong enough for the use of personal protective equipment against falls from a height.

Any trapdoor in floors or ceilings or side doors must be designed and constructed in such a way as to prevent inadvertent opening and must open in a direction that obviates any risk of falling, should they open unexpectedly.

6.3.3. Risk due to objects falling on the carrier

Where there is a risk of objects falling on the carrier and endangering persons, the carrier must be equipped with a protective roof.

6.4. MACHINERY SERVING FIXED LANDINGS

6.4.1. Risks to persons in or on the carrier

The carrier must be designed and constructed in such a way as to prevent risks due to contact between persons and/or objects in or on the carrier with any fixed or moving elements. Where necessary in order to fulfil this requirement, the carrier itself must be completely enclosed with doors fitted with an interlocking device that prevents hazardous movements of the carrier unless the doors are closed. The doors must remain closed if the carrier stops between landings where there is a risk of falling from the carrier.

The machinery must be designed, constructed and, where necessary, equipped with devices in such a way as to prevent uncontrolled upward or downward movement of the carrier. These devices must be able to stop the carrier at its maximum working load and at the foreseeable maximum speed.

The stopping action must not cause deceleration harmful to the occupants, whatever the load conditions.

6.4.2. Controls at landings

Controls, other than those for emergency use, at landings must not initiate movements of the carrier when:

— the control devices in the carrier are being operated,
— the carrier is not at a landing.

6.4.3. Access to the carrier

The guards at the landings and on the carrier must be designed and constructed in such a way as to ensure safe transfer to and from the carrier, taking into consideration the foreseeable range of goods and persons to be lifted.

6.5. MARKINGS

The carrier must bear the information necessary to ensure safety including:

— the number of persons permitted on the carrier,
— the maximum working load.
PART 2 Regulations 7(2)(e) and 8(1)(c)

Annex II: Declarations

1. CONTENT

A. EC DECLARATION OF CONFORMITY OF THE MACHINERY

This declaration and translations thereof must be drawn up under the same conditions as the instructions (see Part 1 of this Schedule (Annex I), section 1.7.4.1(a) and (b)), and must be typewritten or else handwritten in capital letters.

This declaration relates exclusively to the machinery in the state in which it was placed on the market, and excludes components which are added and/or operations carried out subsequently by the final user.

The EC declaration of conformity must contain the following particulars:

1. business name and full address of the manufacturer and, where appropriate, his authorised representative;

2. name and address of the person authorised to compile the technical file, who must be established in the Community;

3. description and identification of the machinery, including generic denomination, function, model, type, serial number and commercial name;

4. a sentence expressly declaring that the machinery fulfils all the relevant provisions of the Directive and where appropriate, a similar sentence declaring the conformity with other Directives and/or relevant provisions with which the machinery complies. These references must be those of the texts published in the Official Journal of the European Union;

5. where appropriate, the name, address and identification number of the notified body which carried out the EC type-examination referred to in Part 9 of this Schedule (Annex IX) and the number of the EC type-examination certificate;

6. where appropriate, the name, address and identification number of the notified body which approved the full quality assurance system referred to in Part 10 of this Schedule (Annex X);

7. where appropriate, a reference to the published harmonised standards used;

8. where appropriate, the reference to other technical standards and specifications used;

9. the place and date of the declaration;

10. the identity and signature of the person empowered to draw up the declaration on behalf of the responsible person.

B. DECLARATION OF INCORPORATION OF PARTLY COMPLETED MACHINERY

This declaration and translations thereof must be drawn up under the same conditions as the instructions (see Part 1 of this Schedule (Annex I), section 1.7.4.1(a) and (b)), and must be typewritten or else handwritten in capital letters.

The declaration of incorporation must contain the following particulars:

1. business name and full address of the manufacturer of the partly completed machinery and, where appropriate, his authorised representative;
2. name and address of the person authorised to compile the relevant technical documentation, who must be established in the Community;

3. description and identification of the partly completed machinery including generic denomination, function, model, type, serial number and commercial name;

4. a sentence declaring which essential health and safety requirements are applied and fulfilled and that the relevant technical documentation is compiled in accordance with part B of Part 7 of this Schedule (Annex VII), and, where appropriate, a sentence declaring the conformity of the partly completed machinery with other relevant Directives. These references must be those of the texts published in the Official Journal of the European Union;

5. an undertaking to transmit, in response to a reasoned request by the national authorities, relevant information on the partly completed machinery. This shall include the method of transmission and shall be without prejudice to the intellectual property rights of the manufacturer of the partly completed machinery;

6. a statement that the partly completed machinery must not be put into service until the final machinery into which it is to be incorporated has been declared in conformity with the provisions of the Directive, where appropriate;

7. the place and date of the declaration;

8. the identity and signature of the person empowered to draw up the declaration on behalf of the responsible person.

2. CUSTODY

The manufacturer of machinery or his authorised representative shall keep the original EC declaration of conformity for a period of at least 10 years from the last date of manufacture of the machinery.

The manufacturer of partly completed machinery or his authorised representative shall keep the original declaration of incorporation for a period of at least 10 years from the last date of manufacture of the partly completed machinery.

PART 3 Regulation 7(2)(f)(ii)

Annex III: CE marking

The CE conformity marking shall consist of the initials “CE” taking the following form:

![CE marking](image)

If the CE marking is reduced or enlarged the proportions shown in the above drawing must be respected.

The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm. The minimum dimension may be waived for small-scale machinery.

The CE marking must be affixed in the immediate vicinity of the name of the responsible person, using the same technique.
Where the full quality assurance procedure prescribed in Part 10 of this Schedule (Annex X) has been applied, the CE marking must be followed by the identification number of the notified body.

**PART 4**

Annex IV: Categories of machinery to which one of the procedures referred to in regulation 11 or 12 must be applied

1. Circular saws (single- or multi-blade) for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:
   1.1. sawing machinery with fixed blade(s) during cutting, having a fixed bed or support with manual feed of the workpiece or with a demountable power feed;
   1.2. sawing machinery with fixed blade(s) during cutting, having a manually operated reciprocating saw-bench or carriage;
   1.3 sawing machinery with fixed blade(s) during cutting, having a built-in mechanical feed device for the workpieces, with manual loading and/or unloading;
   1.4. sawing machinery with movable blade(s) during cutting, having mechanical movement of the blade, with manual loading and/or unloading.
3. Thicknessers for one-side dressing having a built-in mechanical feed device, with manual loading and/or unloading for woodworking.
4. Band-saws with manual loading and/or unloading for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:
   4.1. sawing machinery with fixed blade(s) during cutting, having a fixed or reciprocating-movement bed or support for the workpiece;
   4.2. sawing machinery with blade(s) assembled on a carriage with reciprocating motion.
5. Combined machinery of the types referred to in points 1 to 4 and point 7 of this Annex, for working with wood and material with similar physical characteristics.
6. Hand-fed tenoning machinery with several tool holders for woodworking.
7. Hand-fed vertical spindle moulding machinery for working with wood and material with similar physical characteristics.
8. Portable chainsaws for woodworking.
9. presses, including press-brakes, for the cold working of metals, with manual loading and/or unloading, whose movable working parts may have a travel exceeding 6 mm and a speed exceeding 30 mm/s.
10. Injection or compression plastics-moulding machinery with manual loading or unloading.
11. Injection or compression rubber-moulding machinery with manual loading or unloading.
12. Machinery for underground working of the following types:
12.1. locomotives and brake-vans;

12.2. hydraulic-powered roof supports.

13. Manually loaded trucks for the collection of household refuse incorporating a compression mechanism.

14. Removable mechanical transmission devices including their guards.

15. Guards for removable mechanical transmission devices.


17. Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than three metres.

18. Portable cartridge-operated fixing and other impact machinery.

19. Protective devices designed to detect the presence of persons.

20. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9, 10 and 11 of this Annex.

21. Logic units to ensure safety functions.

22. Roll-over protective structures (ROPS).

23. Falling-object protective structures (FOPS).

PART 5 Regulation 4(2)(c)

Annex V: Indicative list of safety components

1. Guards for removable mechanical transmission devices.

2. Protective devices designed to detect the presence of persons.

3. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9, 10 and 11 of Part 4 of this Schedule (Annex IV).

4. Logic units to ensure safety functions.

5. Valves with additional means for failure detection intended for the control of dangerous movements on machinery.


7. Guards and protective devices designed to protect persons against moving parts involved in the process on the machinery.

8. Monitoring devices for loading and movement control in lifting machinery.

9. Restraint systems to keep persons on their seats.


11. Discharging systems to prevent the build-up of potentially dangerous electrostatic charges.
12. Energy limiters and relief devices referred to in sections 1.5.7, 3.4.7 and 4.1.2.6 of Part 1 of this Schedule (Annex I).

13. Systems and devices to reduce the emission of noise and vibrations.

14. Roll-over protective structures (ROPS).

15. Falling-object protective structures (FOPS).

16. Two-hand control devices.

17. Components for machinery designed for lifting and/or lowering persons between different landings and included in the following list:

(a) devices for locking landing doors;
(b) devices to prevent the load-carrying unit from falling or unchecked upwards movement;
(c) overspeed limitation devices;
(d) energy-accumulating shock absorbers,
   — non-linear, or
   — with damping of the return movement;
(e) energy-dissipating shock absorbers;
(f) safety devices fitted to jacks of hydraulic power circuits where these are used as devices to prevent falls;
(g) electric safety devices in the form of safety switches containing electronic components.

PART 6
Regulation 8(2)(b)

Annex VI: Assembly instructions for partly completed machinery
The assembly instructions for partly completed machinery must contain a description of the conditions which must be met with a view to correct incorporation in the final machinery, so as not to compromise safety and health.

The assembly instructions must be written in an official Community language acceptable to the manufacturer of the machinery in which the partly completed machinery will be assembled, or to his authorised representative.

PART 7
Regulations 7(2)(b) and 8(1)(a)

Annex VII: Technical files

Part A. Technical file for machinery
This part describes the procedure for compiling a technical file. The technical file must demonstrate that the machinery complies with the provisions of the Directive. It must cover the design, manufacture and operation of the machinery to the extent necessary for this assessment. The technical file must be compiled in one or more official Community languages, except for the instructions for the machinery, for which the special provisions of section 1.7.4.1 of Part 1 of this Schedule (Annex I) apply.
1. The technical file shall comprise the following:

(a) a construction file including:

— a general description of the machinery,

— the overall drawing of the machinery and drawings of the control circuits, as well as the pertinent descriptions and explanations necessary for understanding the operation of the machinery,

— full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the machinery with the essential health and safety requirements,

— the documentation on risk assessment demonstrating the procedure followed, including:

(i) a list of the essential health and safety requirements which apply to the machinery,

(ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, when appropriate, the indication of the residual risks associated with the machinery,

— the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,

— any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the responsible person,

— a copy of the instructions for the machinery,

— where appropriate, the declaration of incorporation for included partly completed machinery and the relevant assembly instructions for such machinery,

— where appropriate, copies of the EC declaration of conformity of machinery or other products incorporated into the machinery,

— a copy of the EC declaration of conformity;

(b) for series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of the Directive.

The manufacturer must carry out necessary research and tests on components, fittings or the completed machinery to determine whether by its design or construction it is capable of being assembled and put into service safely. The relevant reports and results shall be included in the technical file.

2. The technical file referred to in point 1 above must be made available to the enforcement authorities for at least 10 years following the date of manufacture of the machinery or, in the case of series manufacture, of the last unit produced.

The technical file does not have to be located in the territory of the Community, nor does it have to be permanently available in material form. However, it must be capable of being assembled and made available within a period of time commensurate with its complexity by the person designated in the EC declaration of conformity.

The technical file does not have to include detailed plans or any other specific information as regards the sub-assemblies used for the manufacture of the machinery unless a knowledge of them is essential for verification of conformity with the essential health and safety requirements.
3. Failure to present the technical file in response to a duly reasoned request by the competent national authorities may constitute sufficient grounds for doubting the conformity of the machinery in question with the essential health and safety requirements.

**Part B. Relevant technical documentation for partly completed machinery**

This part describes the procedure for compiling relevant technical documentation. The documentation must show which provisions of the Directive are applied and fulfilled. It must cover the design, manufacture and operation of the partly completed machinery to the extent necessary for the assessment of conformity with the essential health and safety requirements applied. The documentation must be compiled in one or more official Community languages.

1. Relevant technical documentation shall comprise the following:

   (a) a construction file including:

   — the overall drawing of the partly completed machinery and drawings of the control circuits,

   — full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the partly completed machinery with the applied essential health and safety requirements,

   — the risk assessment documentation showing the procedure followed, including:

     (i) a list of the essential health and safety requirements applied and fulfilled,

     (ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, where appropriate, the indication of the residual risks,

     (iii) the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,

     (iv) any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the responsible person,

     (v) a copy of the assembly instructions for the partly completed machinery;

   (b) for series manufacture, the internal measures that will be implemented to ensure that the partly completed machinery remains in conformity with the essential health and safety requirements applied.

   The manufacturer must carry out necessary research and tests on components, fittings or the partly completed machinery to determine whether by its design or construction it is capable of being assembled and used safely. The relevant reports and results shall be included in the technical file.

2. The relevant technical documentation must be available for at least 10 years following the date of manufacture of the partly completed machinery or, in the case of series manufacture, of the last unit produced, and on request presented to an enforcement authority. It does not have to be located in the territory of the Community, nor does it have to be permanently available in material form. It must be capable of being assembled and presented to the relevant authority by the person designated in the declaration for incorporation.

3. Failure to present the relevant technical documentation in response to a duly reasoned request by an enforcement authority may constitute sufficient grounds for doubting the conformity of the partly completed machinery with the essential health and safety requirements applied and attested.
PART 8  Regulations 10, 11(3), 12(3)(a)

Annex VIII: Assessment of conformity with internal checks on the manufacture of machinery

1. This Annex describes the procedure by which the responsible person, who carries out the obligations laid down in points 2 and 3 below, ensures and declares that the machinery concerned satisfies the relevant provisions of the Directive.

2. For each representative type of the series in question, the responsible person shall draw up the technical file referred to in Part 7 of this Schedule (Annex VII), part A.

3. The manufacturer must take all measures necessary in order that the manufacturing process ensures compliance of the manufactured machinery with the technical file referred to in Annex VII, part A, and with the provisions of the Directive.

PART 9  Regulations 11(3)(b), 12(3)(a), 18(1)

Annex IX: EC type-examination

EC type-examination is the procedure whereby a notified body ascertains and certifies that a representative model of machinery referred to in Part 4 of this Schedule (Annex IV) (hereafter named the type) satisfies the provisions of the Directive.

1. The responsible person must, for each type, draw up the technical file referred to in Part 7 of this Schedule (Annex VII), part A.

2. For each type, the application for an EC type-examination shall be submitted by the responsible person to a notified body of his choice.

   The application shall include:
   — the name and address of the manufacturer and, where appropriate, his authorised representative,
   — a written declaration that the application has not been submitted to another notified body,
   — the technical file.

   Moreover, the applicant shall place at the disposal of the notified body a sample of the type. The notified body may ask for further samples if the test programme so requires.

3. The notified body shall:

   3.1. examine the technical file, check that the type was manufactured in accordance with it and establish which elements have been designed in accordance with the relevant provisions of published harmonised standards, and those elements whose design is not based on the relevant provisions of those standards;

   3.2. carry out or have carried out appropriate inspections, measurements and tests to ascertain whether the solutions adopted satisfy the essential health and safety requirements, where published harmonised standards were not applied;

   3.3. where published harmonised standards were used, carry out or have carried out appropriate inspections, measurements and tests to verify that those standards were actually applied;
3.4. agree with the applicant as to the place where the check that the type was manufactured in accordance with the examined technical file and the necessary inspections, measurements and tests will be carried out.

4. If the type satisfies the provisions of the Directive, the notified body shall issue the applicant with an EC type-examination certificate. The certificate shall include the name and address of the manufacturer and his authorised representative, the data necessary for identifying the approved type, the conclusions of the examination and the conditions to which its issue may be subject.

The manufacturer and the notified body shall retain a copy of this certificate, the technical file and all relevant documents for a period of 15 years from the date of issue of the certificate.

5. If the type does not satisfy the provisions of the Directive, the notified body shall refuse to issue the applicant with an EC type-examination certificate, giving detailed reasons for its refusal. It shall inform the applicant, the other notified bodies and the Member State which notified it. An appeal procedure must be available.

6. The applicant shall inform the notified body which retains the technical file relating to the EC type-examination certificate of all modifications to the approved type. The notified body shall examine these modifications and shall then either confirm the validity of the existing EC type-examination certificate or issue a new one if the modifications are liable to compromise conformity with the essential health and safety requirements or the intended working conditions of the type.

7. The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EC type-examination certificates. On reasoned request, the Commission and the Member States may obtain a copy of the technical file and the results of the examinations carried out by the notified body.

8. Files and correspondence referring to the EC type-examination procedures shall be written in the official Community language(s) of the Member State where the notified body is established or in any other official Community language acceptable to the notified body.

9. Validity of the EC type-examination certificate

9.1. The notified body has the ongoing responsibility of ensuring that the EC type-examination certificate remains valid. It shall inform the manufacturer of any major changes which would have an implication on the validity of the certificate. The notified body shall withdraw certificates which are no longer valid.

9.2. The manufacturer of the machinery concerned has the ongoing responsibility of ensuring that the said machinery meets the corresponding state of the art.

9.3. The manufacturer shall request from the notified body the review of the validity of the EC type-examination certificate every five years.

If the notified body finds that the certificate remains valid, taking into account the state of the art, it shall renew the certificate for a further five years.

The manufacturer and the notified body shall retain a copy of this certificate, of the technical file and of all the relevant documents for a period of 15 years from the date of issue of the certificate.

9.4. In the event that the validity of the EC-type examination certificate is not renewed, the manufacturer shall cease the placing on the market of the machinery concerned.
PART 10 Regulations 11(3)(c), 12(3)(b), 18(1)

Annex X: Full quality assurance

This Annex describes the conformity assessment of machinery referred to in Part 4 of this Schedule (Annex IV), manufactured using a full quality assurance system, and the procedure whereby a notified body assesses and approves the quality system and monitors its application.

1. The manufacturer must operate an approved quality system for design, manufacture, final inspection and testing, as specified in point 2 of this Annex, and shall be subject to the surveillance referred to in point 3 of this Annex.

2. Quality system

2.1. The responsible person shall lodge an application for assessment of his quality system to a notified body of his choice.

The application shall contain:

— the name and address of the manufacturer and, where appropriate, his authorised representative,

— the places of design, manufacture, inspection, testing and storage of the machinery,

— the technical file described in Part 7 of this Schedule (Annex VII), Part A, for one model of each category of machinery referred to in Part 4 of this Schedule (Annex IV) which he intends to manufacture,

— the documentation on the quality system,

— a written declaration that the application has not been submitted to another notified body.

2.2. The quality system must ensure conformity of the machinery with the provisions of the Directive. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner, in the form of measures, procedures and written instructions. The documentation on the quality system must permit a uniform interpretation of the procedural and quality measures, such as quality programmes, plans, manuals and records.

It must contain, in particular, an adequate description of:

— the quality objectives, the organisational structure, and the responsibilities and powers of the management with regard to the design and quality of the machinery,

— the technical design specifications, including standards that will be applied and, where published harmonised standards are not applied in full, the means that will be used to ensure that the essential health and safety requirements are fulfilled,

— the design inspection and design verification techniques, processes and systematic actions that will be used when designing machinery covered by the Directive,

— the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,

— the inspections and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,

— the quality records, such as inspection reports and test data, calibration data, and reports on the qualifications of the personnel concerned,
— the means of monitoring the achievement of the required design and quality of the machinery, as well as the effective operation of the quality system.

2.3. The notified body shall assess the quality system to determine whether it satisfies the requirements of point 2.2 above.

The elements of the quality system which conform to the relevant harmonised standard shall be presumed to conform to the corresponding requirements referred to in point 2.2.

The team of auditors must have at least one member who is experienced in the assessment of the technology of the machinery. The assessment procedure shall include an inspection to be carried out at the manufacturer’s premises. During the assessment, the team of auditors shall carry out a review of the technical files referred to in point 2.1 above, second paragraph, third indent to ensure their compliance with the applicable health and safety requirements.

The responsible person shall be notified of the decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision. An appeal procedure must be available.

2.4. The manufacturer shall undertake to fulfil the obligations arising from the quality system as approved and to ensure that it remains appropriate and effective.

The responsible person shall inform the notified body which approved the quality system of any planned change to it.

The notified body shall evaluate the proposed changes and decide whether the modified quality assurance system will continue to satisfy the requirements referred to in point 2.2, or whether a re-assessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3. Surveillance under the responsibility of the notified body

3.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

3.2. The manufacturer shall, for inspection purposes, allow the notified body access to the places of design, manufacture, inspection, testing and storage, and shall provide it with all necessary information, such as:

— the documentation concerning the quality system,

— the quality records provided for in that part of the quality system concerned with design, such as the results of analyses, calculations, tests, etc.,

— the quality records provided for in that part of the quality system concerned with manufacture, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.

3.3. The notified body shall conduct periodic audits to make sure that the manufacturer is maintaining and applying the quality system; it shall provide the manufacturer with an audit report. The frequency of the periodic audits shall be such that a full reassessment is carried out every three years.

3.4. Moreover, the notified body may pay the manufacturer unannounced visits. The need for these additional visits and their frequency will be determined on the basis of a visit monitoring system managed by the notified body. In particular, the following factors will be taken into account in the visits monitoring system:
— the results of previous surveillance visits,
— the need to monitor remedial measures,
— where appropriate, special conditions attaching to approval of the system,
— significant modifications in the organisation of the manufacturing process, measures or techniques.

On the occasion of such visits, the notified body may, if necessary, carry out tests or have them carried out in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if a test was carried out, with a test report.

4. The responsible person shall keep available for the national authorities, for a period of ten years from the last date of manufacture:
— the documentation referred to in point 2.1 above,
— the decisions and reports of the notified body referred to in point 2.4 above, third and fourth subparagraphs, and in points 3.3 and 3.4 above.

PART 11 Regulation 16(5)

Annex XI: Minimum criteria to be taken into account by Member States for the notification of bodies

1. The body, its director and the staff responsible for carrying out the verification tests shall not be the designer, manufacturer, supplier or installer of machines which they inspect, nor the authorised representative of any of these parties. They shall not become involved, either directly or as authorised representatives, in the design, construction, marketing or maintenance of the machines. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.

2. The body and its staff shall carry out the verification tests with the highest degree of professional integrity and technical competence and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.

3. For each category of machinery for which it is notified, the body must possess personnel with technical knowledge and sufficient and appropriate experience to perform a conformity assessment. It must have the means necessary to complete the technical and administrative tasks connected with implementation of the checks in an appropriate manner; it must also have access to the equipment necessary for the exceptional checks.

4. The staff responsible for inspection shall have:
— sound technical and vocational training,
— satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests,
— the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.

5. The impartiality of inspection staff shall be guaranteed. Their remuneration shall not depend on the number of tests carried out or on the results of such tests.
6. The body shall satisfy the Secretary of State that it has adequate civil liability insurance.

7. The staff of the body shall be bound to observe professional secrecy with regard to all information obtained in carrying out its tasks (except vis-à-vis the Secretary of State) under these Regulations.

8. Notified bodies shall participate in coordination activities. They shall also take part directly or be represented in European standardisation, or ensure that they know the situation in respect of relevant standards.

SCHEDULE 3 Regulations 4(1)(c) and 5(e)

PRODUCTS TO WHICH THE REGULATIONS DO NOT APPLY

These Regulations do not apply to—

(a) safety components which are—
   (i) intended to be used as spare parts to replace identical components; and
   (ii) supplied by the manufacturer of the original machinery;
(b) equipment specifically for use in fairgrounds and/or amusement parks;
(c) machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity;
(d) weapons, including firearms;
(e) the following means of transport—
   (i) agricultural and forestry tractors, in respect of the risks covered by Directive 2003/37/EC(a);
   (iii) vehicles covered by Directive 2002/24/EC of the European Parliament and of the Council of 18 March 2002 relating to the type-approval of two or three-wheel motor vehicles(c);
   (iv) motor vehicles exclusively intended for competition; and
   (v) means of transport by air, on water and on rail networks, excluding, in the case of the means of transport specified in paragraphs (i) to (iii) and paragraph (v), any machinery mounted on them;
(f) seagoing vessels, mobile offshore units and machinery installed on board such vessels or units;
(g) machinery specially designed and constructed for military or police purposes;
(h) machinery specially designed and constructed for research purposes for temporary use in laboratories;
(i) mine winding gear;
(j) machinery intended to move performers during artistic performances;
(k) electrical and electronic products falling within the following areas, insofar as they are covered by Council Directive 2006/95/EC of 12 December 2006 on the harmonisation of

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(c) O.J. No. L 49, 22.2. 2003, p.23.
the laws of Member States relating to electrical equipment designed for use within certain
voltage limits—
(i) household appliances intended for domestic use,
(ii) audio and video equipment,
(iii) information technology equipment,
(iv) ordinary office machinery,
(v) low-voltage switchgear and control gear,
(vi) electric motors; and
(l) the following types of high-voltage electrical equipment—
   (i) switch gear and control gear, and
   (ii) transformers.

SCHEDULE 4

APPEALS AGAINST NOTIFIED BODY DETERMINATIONS
UNDER REGULATION 18(4)

1. A manufacturer (“an appellant”) may appeal against a determination of a UK notified body
under regulation 18(4) (“the determination”) on the grounds that the UK notified body (“the
respondent”) made a material error of law or fact.

2. Any appeal made under paragraph 1 (“an appeal”) shall be—
(a) made to the Secretary of State; and
(b) heard by a person appointed by the Secretary of State, on such terms as he sees fit, to hear
one or more appeals (an “Appeal Officer”).

In this Schedule, “the Appeal Officer” means the person who hears a particular appeal.

3. No person shall be appointed as an Appeal Officer unless the Secretary of State considers that
he will be able (either by virtue of his own knowledge and experience or by availing himself of
sources of independent technical or legal expertise to which he has ready access) to reach
independent, impartial and properly informed decisions on the appeals that he is appointed to hear.

4. An appeal must be made by sending a notice of appeal to the Secretary of State so that it is
received within one month of the date upon which the determination was communicated to the
appellant.

5. On receiving the notice of appeal, the Secretary of State must—
(a) send a copy of the notice to the respondent;
(b) send an acknowledgement of its receipt to the appellant;
(c) forward the notice of appeal to the Appeal Officer endorsed with the date of receipt; and
(d) notify the appellant and the respondent of the arrangements for communicating with the
Appeal Officer.

6. The notice of appeal must—
(a) state the name and address of the appellant and an address for service in the United
Kingdom;
(b) concisely state the grounds for the appeal and the arguments supporting each ground;
(c) contain a schedule listing any documents annexed to it;
(d) be accompanied by a copy of the determination and, as far as practicable, every other
document on which the appellant relies;
(e) be signed and dated by the appellant, or on his behalf by his duly authorised officer or his legal representative.

7. The respondent may make a written response to the notice of appeal. Any such written response must be sent to the Appeal Officer so that it is received within one month of the date on which the Secretary of State received the notice of appeal or such further time as the Appeal Officer may allow.

8. The Appeal Officer must send a copy of the written response to the appellant.

9. The Appeal Officer may—
(a) give the appellant and the respondent the opportunity to make further written or oral representations; and
(b) specify the time and manner in which such further representations are to be made.

10. The Appeal Officer may—
(a) make enquiries of any person;
(b) receive representations from any person;
(c) hold any meeting or hearing; and
(d) subject to this Schedule, follow such practice and procedure, as he thinks fit, having regard to the just, expeditious and economical conduct of the appeal.

11. The Appeal Officer may specify the time and place at which any meeting or hearing is to be held.

12. In determining an appeal, the Appeal Officer must—
(a) dismiss the appeal,
(b) allow the appeal, or
(c) remit the case to the respondent.

13. Where a case is remitted the respondent must reconsider it in accordance with any rulings of law and findings of fact made by the Appeal Officer.

14. The Appeal Officer may dismiss an appeal at any stage if he considers that—
(a) the notice of appeal discloses no valid ground of appeal;
(b) the notice of appeal fails to comply with the requirements of regulation 18; or
(c) the appellant is not entitled to bring the appeal.

15. The Appeal Officer must dismiss an appeal if he considers that the appeal was not brought within the time limit imposed by paragraph 4 unless he is satisfied that the circumstances are exceptional.

16. The Appeal Officer may dismiss an appeal at any stage at the request of the appellant.

17. The Appeal Officer must give the appellant and the respondent reasons for any decision to—
(a) dismiss an appeal;
(b) allow an appeal; or
(c) remit a case to the respondent.
SCHEDULE 5

ENFORCEMENT

General duties of enforcement authorities

1. Except as specified in paragraph 3, it shall be the duty of the Health and Safety Executive to make adequate arrangements for the enforcement of these Regulations in Great Britain in relation to machinery and partly completed machinery for use at work.

2. Except as specified in paragraph 3, it shall be the duty of every local weights and measures authority in Great Britain to enforce these Regulations within its area in relation to machinery or partly completed machinery which is not for use at work.

3. It shall be the duty of the Office of Rail Regulation to make adequate arrangements for the enforcement of these Regulations in Great Britain where the Health and Safety (Enforcing Authority for Railways and Other Guided Transport Systems) Regulations 2006 make it the enforcing authority, within the meaning of section 18(7) of the 1974 Act, in relation to machinery or partly completed machinery for use in the operation of a railway, tramway or any other system of guided transport, as defined in those Regulations.

4. It shall be the duty of the Health and Safety Executive for Northern Ireland to make adequate arrangements for the enforcement of these Regulations in Northern Ireland in relation to machinery and partly completed machinery for use at work.

5. It shall be the duty of every district council in Northern Ireland to enforce these Regulations within its area in relation to machinery or partly completed machinery which is not for use at work.

6. The Secretary of State may enforce these Regulations in relation to machinery or partly completed machinery which is not for use at work in cases where the Office of Rail Regulation is not the enforcement authority.

Powers of the Health and Safety Executive and the Office of Rail Regulation as enforcement authorities

7. In relation to the enforcement of these Regulations by the Health and Safety Executive or the Office of Rail Regulation—
   (a) sections 19 to 28, 33 to 35, 38, 39, 41 and 42 of the 1974 Act shall apply as provided in paragraph 8; and
   (b) sections 36(1) and (2) and 37 of the 1974 Act shall apply in relation to offences under section 33 as applied to these Regulations and modified by paragraph 8.

8. For the purposes of the enforcement of these Regulations by the Health and Safety Executive, and in respect of any related proceedings for contravention of these Regulations, the provisions specified in paragraph 7(a) and (b) shall apply as if—
   (a) references to relevant statutory provisions were references to those provisions as modified by this paragraph and to these Regulations;
   (b) references to articles, substances, articles and substances, or plant, were references to machinery or partly completed machinery, or a machine or partly completed machine, as the context may require;
   (c) references to an “enforcing authority” were references to the Health and Safety Executive;
   (d) references to the field of responsibility of an enforcing authority, however expressed, were omitted;
   (e) in section 20, subsection (3) were omitted;
(f) section 22, as well as permitting an inspector to serve a prohibition notice in the circumstances specified in section 22(2), permitted an inspector to serve a prohibition notice in any case where—
   (i) a responsible person has failed to comply with the requirements of these Regulations in relation to CE marking; and
   (ii) the responsible person—
      (aa) has been served with a notice under regulation 20(2), or an improvement notice under section 21, in respect of that failure; and
      (bb) has continued to fail to comply with those requirements after the period for remedying the contravention specified in the improvement notice;
(g) in section 23, subsections (3), (4) and (6) were omitted;
(h) in section 33—
   (i) in subsection (1) the whole of paragraphs (a) to (d) were omitted;
   (ii) subsection (1A) were omitted;
   (iii) in subsection (2), the reference to paragraph (d) of subsection (1) were omitted;
   (iv) subsection (2A) were omitted;
   (v) for subsection (3) there were substituted the following—
   “(3) A person guilty of an offence under any paragraph of subsection (1) not mentioned in subsection (2), or of an offence under subsection (1)(e) not falling within that subsection, shall be liable—
   (a) on summary conviction, to a fine not exceeding level 5 on the standard scale; or
   (b) on conviction on indictment—
      (i) in the case of an offence under subsection (1)(g) or of an offence under subsection (1)(j), to imprisonment for a term not exceeding two years, or a fine, or both; or
      (ii) in all other cases, to a fine.”; and
   (vi) subsection (4) were omitted;
(i) in section 34—
   (i) paragraphs (a) and (b) were omitted from subsection (1); and
   (ii) in subsection (3) for “six months” there were substituted “twelve months”; and
(j) in section 42, subsections (4) and (5) were omitted.

Powers of the Health and Safety Executive for Northern Ireland as an enforcement authority

9. In relation to the enforcement of these Regulations by the Health and Safety Executive for Northern Ireland—
   (a) Articles 21 to 33, 35, 36, 38 and 39 of the 1978 Order shall apply as provided in paragraph 10; and
   (b) Articles 34(1) and (2) and 34A of the 1978 Order shall apply in relation to offences under Article 31 as applied to these Regulations and modified by paragraph 10.

10. For the purposes of the enforcement of these Regulations by the Health and Safety Executive for Northern Ireland, and in respect of any related proceedings for contravention of these Regulations, the provisions specified in paragraph 9(a) and (b) shall apply as if—
   (a) references to relevant statutory provisions were references to those provisions as modified by this paragraph and to these Regulations;
(b) references to articles, substances, articles and substances, or plant, were references to machinery or partly completed machinery, or a machine or partly completed machine, as the context may require;

(c) references to an “enforcing authority” or to its field of responsibility (however expressed) or to “the Department concerned” were to the Health and Safety Executive for Northern Ireland;

(d) in Article 22, paragraph (3) were omitted;

(e) Article 24, as well as permitting an inspector to serve a prohibition notice in the circumstances specified in Article 24(2), permitted an inspector to serve a prohibition notice in any case where—

(i) a responsible person has failed to comply with the requirements of these Regulations in relation to CE marking; and

(ii) the responsible person—

(aa) has been served with a notice under regulation 20(2), or an improvement notice under Article 23, in respect of that failure; and

(bb) has continued to fail to comply with those requirements after the period for remedying the contravention specified in the improvement notice;

(f) in Article 25, paragraphs (3), (4) and (5) were omitted;

(g) in Article 31—

(i) in paragraph (1), the whole of sub-paragraphs (a) to (d) were omitted;

(ii) paragraph (1A) were omitted;

(iii) in paragraph (2), the reference to sub-paragraph (d) of paragraph (1) were omitted;

(iv) paragraph (2A) were omitted;

(v) for paragraph (4) there were substituted the following—

“(4) A person guilty of an offence under any sub-paragraph of paragraph (1) not mentioned in paragraph (2) or of an offence under paragraph (1)(e) not falling within paragraph (2) shall be liable—

(a) on summary conviction, to a fine not exceeding £2000; or

(b) on conviction on indictment—

(i) in the case of an offence under paragraph (1)(g) or of an offence under paragraph (1)(j), to imprisonment for a term not exceeding two years, or a fine, or both; or

(ii) in all other cases, to a fine.”; and

(vi) paragraph (5) were omitted;

(h) in Article 32—

(i) sub-paragraphs (a) and (b) were omitted from paragraph (1); and

(ii) in paragraph (3), for “six months” there were substituted “twelve months”; and

(i) in Article 39, paragraphs (4) and (5) were omitted.

Powers of other enforcement authorities

11. In relation to the enforcement of these Regulations by local weights and measures authorities, Northern Ireland district councils or the Secretary of State—

(a) sections 14, 15, 28 to 35, 37, 44 and 47 of the 1987 Act shall apply as provided in paragraph 12;

(b) sections 39 and 40 shall apply in relation to offences under section 32 as applied to these Regulations and modified by paragraph 12.
12. For the purposes of the enforcement of these Regulations by local weights and measures authorities, Northern Ireland district councils or the Secretary of State, and in respect of any related proceedings for contravention of these Regulations, the provisions specified in paragraph 11(a) and (b) shall apply as if—

(a) references to safety provisions were references to these Regulations;
(b) references to goods were references to machinery or partly completed machinery, or a machine or partly completed machine, as the context may require;
(c) references to an “enforcement authority” were to the local weights and measures authority or Northern Ireland district council concerned, or to the Secretary of State, as appropriate;
(d) in section 14, in subsection (6), for “six months” there were substituted “three months”;
(e) in sections 28, 29, 30, 33, 34 and 35, the words “or any provision made by or under Part III of this Act”, on each occasion that they occur, were omitted;
(f) in section 28, subsections (3), (4) and (5) were omitted;
(g) in section 29, subsection (4) were omitted; and
(h) in section 30, subsections (7) and (8) were omitted.

13. In relation to proceedings for an offence in relation to machinery or partly completed machinery which is not for use at work—

(a) in Great Britain, section 34 of the 1974 Act shall apply as if—

(i) paragraphs (a) and (b) of subsection (1) were omitted;
(ii) references to an “enforcing authority” were references to local weights and measures authorities and the Secretary of State, and “responsible enforcing authority” were construed accordingly;
(iii) references to “relevant statutory provisions” were references to these Regulations; and
(iv) in subsection (3), for “six months” there were substituted “twelve months”; and

(b) in Northern Ireland, Article 32 of the 1978 Order shall apply as if—

(i) sub-paragraphs (a) and (b) of paragraph (1) were omitted;
(ii) references to an “enforcing authority” were references to Northern Ireland district councils, and “responsible enforcing authority” were construed accordingly;
(iii) references to “relevant statutory provisions” were references to these Regulations; and
(iv) in paragraph (3), for “six months” there were substituted “twelve months”.

Forfeiture: England and Wales and Northern Ireland

14.—(1) An enforcement authority in England and Wales or Northern Ireland may apply under this paragraph for an order for the forfeiture of any machinery or partly completed machinery on the grounds that there has been a contravention of regulation 7 or 8 in relation to it.

(2) An application under this paragraph may be made—

(a) where proceedings have been brought in a magistrates’ court in respect of an offence in relation to some or all of the machinery or partly completed machinery under regulation 21(1), to that court;
(b) where an application with respect to some or all of the machinery or partly completed machinery has been made to a magistrates’ court under section 15 or 33 of the 1987 Act as applied for the purposes of the enforcement of these Regulations by paragraph 11, to that court; and
(c) where no application for the forfeiture of the machinery or partly completed machinery has been made under sub-paragraph (a) or (b) above, by way of complaint to a magistrates’ court.
(3) On an application under this paragraph the court shall make an order for the forfeiture of the machinery or partly completed machinery only if it is satisfied that there has been a contravention of regulation 7 or 8 in relation to it.

(4) For the avoidance of doubt it is hereby declared that a court may infer for the purposes of this paragraph that there has been a contravention of regulation 7 or 8 in relation to any machinery or partly completed machinery if it is satisfied that that regulation has been contravened in relation to a machine or partly completed machine which is representative of that machinery or partly completed machinery (whether by reason of being of the same design or part of the same consignment or batch or otherwise).

(5) Any person aggrieved by an order made under this paragraph by a magistrates’ court, or by a decision of such court not to make such an order, may appeal against that order or decision—

(a) in England and Wales, to the Crown Court;

(b) in Northern Ireland, to the county court,

and an order so made may contain such provision as appears to the court to be appropriate for delaying the coming into force of an order pending the making and determination of any appeal (including any application under section 111 of the Magistrates’ Courts Act 1980, or Article 146 of the Magistrates’ Courts (Northern Ireland) Order 1981 (statement of case)).

(6) Subject to sub-paragraph (7) below, where any machinery or partly completed machinery is forfeited under this paragraph it shall be destroyed in accordance with such directions as the court may give.

(7) On making an order under this paragraph a magistrates’ court may, if it considers it appropriate to do so, direct that the machinery or partly completed machinery to which the order relates shall (instead of being destroyed) be released, to such person as the court may specify, on condition that that person—

(a) does not supply the machinery or partly completed machinery to any person otherwise than—

(i) to a person who carries on a business of buying machinery or partly completed machinery of the same description as that machinery or partly completed machinery and repairing or reconditioning it; or

(ii) as scrap (that is to say, for the value of materials included in the machinery or partly completed machinery rather than for the value of the machinery or partly completed machinery itself); and

(b) complies with any order to pay costs or expenses (including any order under section 35 of the 1987 Act as applied for the purposes of the enforcement of these Regulations by paragraph 11 above) which has been made against that person in the proceedings for the order for forfeiture.

Forfeiture: Scotland

15.—(1) In Scotland a sheriff may make an order for forfeiture of any machinery or partly completed machinery in relation to which there has been a contravention of any provision of regulation 7 or 8—

(a) on an application by the procurator-fiscal made in the manner specified in section 310 of the Criminal Procedure (Scotland) Act 1975; or

(b) where a person is convicted of any offence in respect of any such contravention, in addition to any other penalty which the sheriff may impose.

(2) The procurator-fiscal making an application under sub-paragraph (1)(a) above shall serve on any person appearing to him to be the owner of, or otherwise to have an interest in, machinery or partly completed machinery to which the application relates a copy of the application, together with a notice giving him the opportunity to appear at the hearing of the application to show cause why the machinery or partly completed machinery should not be forfeited.
(3) Service under sub-paragraph (2) above shall be carried out, and such service may be proved, in the manner specified for citation of an accused in summary proceedings under the Criminal Procedure (Scotland) Act 1975.

(4) Any person upon whom a notice is served under sub-paragraph (2) above and any other person claiming to be the owner of, or otherwise to have an interest in, the machinery or partly completed machinery to which an application under this paragraph relates shall be entitled to appear at the hearing of the application to show cause why the machinery or partly completed machinery as the case may be should not be forfeited.

(5) The sheriff shall not make an order following an application under sub-paragraph (1)(a) above—

(a) if any person on whom notice is served under sub-paragraph (2) above does not appear, unless service of the notice on that person is proved; or

(b) if no notice under sub-paragraph (2) above has been served, unless the court is satisfied that in the circumstances it was reasonable not to serve notice on any person.

(6) The sheriff shall make an order under this paragraph only if he is satisfied that there has been a contravention in relation to the machinery or partly completed machinery of regulation 7 or 8.

(7) For the avoidance of doubt it is declared that the sheriff may infer for the purposes of this paragraph that there has been a contravention of regulation 7 or 8 in relation to any machinery or partly completed machinery if he is satisfied that regulation 7 or 8 has been contravened in relation to a machine or partly completed machine which is representative of that machinery or partly completed machinery (whether by reason of being of the same design or part of the same consignment or batch or otherwise).

(8) Where an order for the forfeiture of any machinery or partly completed machinery is made following an application by the procurator-fiscal under sub-paragraph (1)(a) above, any person who appeared, or was entitled to appear, to show cause why it should not be forfeited may, within twenty-one days of the making of the order, appeal to the High Court by Bill of Suspension on the ground of an alleged miscarriage of justice; and section 452(4)(a) to (e) of the Criminal Procedure (Scotland) Act 1975 shall apply to an appeal under this sub-paragraph as it applies to a stated case under Part II of that Act.

(9) An order following an application under sub-paragraph (1)(a) above shall not take effect—

(a) until the end of the period of twenty-one days beginning with the day after the day on which the order is made; or

(b) if an appeal is made under sub-paragraph (8) above within that period, until the appeal is determined or abandoned.

(10) An order under sub-paragraph (1)(b) shall not take effect—

(a) until the end of the period within which an appeal against the order could be brought under the Criminal Procedure (Scotland) Act 1975; or

(b) if an appeal is made within that period, until the appeal is determined or abandoned.

(11) Subject to sub-paragraph (12) below, machinery or partly completed machinery forfeited under this paragraph shall be destroyed in accordance with such directions as the sheriff may give.

(12) If he thinks fit, the sheriff may direct the machinery or partly completed machinery to be released to such person as he may specify, on condition that that person does not supply it to any person otherwise than—

(a) to a person who carries on a business of buying machinery or partly completed machinery of the same description as that machinery or partly completed machinery and repairing or reconditioning it; or

(b) as scrap (that is to say, for the value of materials included in the machinery or partly completed machinery rather than for the value of the machinery or partly completed machinery itself).
Duty of enforcement authority to inform Secretary of State of action taken

16. Any enforcement authority (other than the Secretary of State) which takes action (whether under these Regulations or otherwise) to prohibit or restrict the placing on the market or putting into service of any machinery or partly completed machinery which bears the CE marking must immediately inform the Secretary of State of the action taken, and the reasons for it, with a view to that information being passed by him to the Commission.

Savings

17. Nothing in these Regulations prevents an enforcement authority from taking any action (whether by way of investigation, prosecution or otherwise) which the provisions of the 1974 Act, the 1978 Order or the 1987 Act, apart from these Regulations and any modifications made by them for the purposes of these Regulations, permit that enforcement authority to take in respect of any machinery or partly completed machinery.

18. Nothing in these Regulations shall authorise an enforcement authority to bring proceedings in Scotland for an offence.

SCHEDULE 6

Regulation 24

AMENDMENTS TO THE LIFTS REGULATIONS 1997

1. In this Schedule, any reference to a regulation or Schedule is a reference to the relevant regulation of or Schedule to the Lifts Regulations 1997.


3. Before the definition of “CE marking” in regulation 2(2), there is inserted—

“carrier” means a part of a lift by which persons or goods are transported in order to be lifted or lowered;”.

4. The definition of “lift” in regulation 2(2) is amended as follows:

(a) in the first line of the definition, for “an appliance”, there is substituted “a lifting appliance”; and

(b) in the third indent, there is substituted—

(i) for each occurrence of “car” there is substituted “carrier”; and

(ii) after “a person inside”, there is inserted “the carrier”.

5. In Schedule 1—

(a) for each reference to “Directive 98/37/EC” in section 1.1 (the head note and both references in the text) and section 5 of Annex I to the Lifts Directive (Directive 95/16/EC), there is substituted “Directive 2006/42/EC”; and

(b) before the first sentence of paragraph 1.2, the following is inserted—

“The carrier of each lift must be a car.”.

6. For the lifts specified in Schedule 14 (Excluded lifts) there is substituted the following—

1. Lifting appliances whose speed is not greater than 0.15m/s.

2. Construction site hoists.

3. Cableways, including funicular railways.

4. Lifts specially designed and constructed for military or police purposes.
5. Lifting appliances from which work can be carried out.


7. Lifting appliances intended for lifting performers during artistic performances.

8. Lifting appliances fitted in means of transport.

9. Lifting appliances connected to machinery and intended exclusively for access to workstations including maintenance and inspection points on the machinery.

10. Rack and pinion trains.

11. Escalators and mechanical walkways.”.

SCHEDULE 7

CONSEQUENTIAL AMENDMENTS

The Provision and Use of Work Equipment Regulations 1998

1. In Schedule 1 to the Provision and Use of Work Equipment Regulations 1998(a)—
   (a) the entry relating to the 1992 Regulations is deleted; and
   (b) a new entry is inserted at the end, as follows—
       (i) in the first column: “The Supply of Machinery (Safety) Regulations 2008”; and
       (ii) in the second column, the S.I. number of these Regulations.

The Lifting Operations and Lifting Equipment Regulations 1998

2. In regulation 2(1) of the Lifting Operations and Lifting Equipment Regulations 1998(b)—
   (a) the definition of “the 1992 Regulations” is deleted; and
   (b) in sub-paragraph (a) of the definition of “EC declaration of conformity”, for “regulation 22 of the 1992 Regulations”, there is substituted “Section A of part 1 of Part 2 of Schedule 2 to the Supply of Machinery (Safety) Regulations 2008”.

The Pressure Equipment Regulations 1999

3. For the first indent in paragraph 6 of Schedule 1 to the Pressure Equipment Regulations 1999(c), there is substituted—

The Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001

4.—(1) For the definition of “equipment for use outdoors”, in regulation 2(2) of the Noise Emission in the Environment by Equipment for use Outdoors Regulations 2001(d) (“the 2001 Regulations”) there is substituted the following—
   ““equipment for use outdoors” means all machinery, interchangeable equipment and safety components, as defined, respectively, in Article 2(a), (b) and (c) of Directive 2006/42/EC of

(a) S.I. 1998/2306.
(b) S.I. 1998/2307.
(c) S.I. 1999/2001.
(d) S.I. 2001/1701.
the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC, that is to say—

(a) assemblies which—
   (i) are fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, and
   (ii) consist of linked parts or components, at least one of which moves, and which are joined together for a specific application, regardless of whether they are fitted with components to connect them on site or to sources of energy and motion, or are ready to be installed and able to function without being either mounted on a means of transport or installed in a building or structure;

(b) assemblies which are composed of one or more assemblies, each of which—
   (i) falls within sub-paragraph (i); or
   (ii) constitutes partly completed machinery, and which, in order to achieve a common end, are arranged and controlled so that they function as an integral whole; and

(c) assemblies—
   (i) which consist of linked parts or components, at least one of which moves and which are joined together;
   (ii) which are intended for lifting loads, and whose only power source is directly applied human effort;

(d) devices which, after the putting into service of machinery or of a tractor, are assembled with that machinery or tractor by the operator himself in order to change its function or attribute a new function, in so far as this equipment is not a tool; and

(e) components which—
   (i) serve to fulfil a safety function;
   (ii) which are independently placed on the market;
   (iii) the failure or malfunction of which endangers the safety of persons; and
   (iv) which are not necessary in order for the machinery to function, or for which other components which do not fall within sub-paragraphs (i) to (iii) may be substituted in order for the machinery to function,

   to the extent that such machinery, interchangeable equipment or safety components are either self-propelled or can be moved and which, irrespective of the driving element(s), are intended to be used, according to their type, in the open air and which contribute to environmental noise exposure, including non-powered equipment for industrial or environmental applications which is intended, according to its type, to be used outdoors and which contributes to environmental noise exposure;”.

(2) In regulation 3(2) of the 2001 Regulations, for “paragraphs 1.5.8 and 1.7.4(f) of Schedule 3 to the Supply of Machinery (Safety) Regulations 1992” there is substituted “paragraphs 1.5.8 and 1.7.4(u) of Part 1 of Schedule 2 to the Supply of Machinery (Safety) Regulations 2008”.


   (a) the entry relating to the 1992 Regulations is deleted; and
   (b) a new entry is inserted at the end, as follows—

(a) S.I. 2004/693.
“The Supply of Machinery (Safety) Regulations 2008.”.

The Merchant Shipping and Fishing Vessels (Provision and Use of Work Equipment) Regulations 2006

6. In Schedule 1 to the Merchant Shipping and Fishing Vessels (Provision and Use of Work Equipment) Regulations 2006(a)—

(a) the entry relating to the 1992 Regulations is deleted; and

(b) a new entry is inserted at the end, as follows—

(i) in the left-hand column: “The Supply of Machinery (Safety) Regulations 2008”; and

(ii) in the right-hand column, the S.I. number of these Regulations.

SCHEDULE 8

Regulation 26(2)(i)

CONSEQUENTIAL DISAPPLICATIONS

Part 1: Regulations made under the Mines and Quarries Act 1954

<table>
<thead>
<tr>
<th>Title</th>
<th>Reference</th>
<th>Extent of Disapplication</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Loch Aline Mine (Diesel Vehicles) Special Regulations 1958</td>
<td>S.I. 1958/1678</td>
<td>Regulations 4 to 6</td>
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<tr>
<td>The Middleton-by-Wirksworth Limestone Mine (Diesel Vehicles) Special Regulations 1959</td>
<td>S.I. 1959/1520</td>
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<td>The Woodside Nos 2 and 3 Mine (Diesel Vehicles) Special Regulations 1960</td>
<td>S.I. 1960/1291</td>
<td>Regulations 4 to 6</td>
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<tr>
<td>The Grimethorpe Mine (Diesel Vehicles) Special Regulations 1961</td>
<td>S.I. 1961/2444</td>
<td>Regulations 4 to 6</td>
</tr>
<tr>
<td>The Lynemouth Mine (Diesel Vehicles and Storage Battery Vehicles) Special Regulations 1961</td>
<td>S.I. 1961/2445</td>
<td>Regulations 4 to 7</td>
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<tr>
<td>The Calverton Mine (Diesel Vehicles) Special Regulations 1962</td>
<td>S.I. 1962/931</td>
<td>Regulations 4 to 6</td>
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<tr>
<td>The Brightling Mine (Diesel Vehicles) Special Regulations 1962</td>
<td>S.I. 1962/1094</td>
<td>Regulations 5 to 7</td>
</tr>
<tr>
<td>The Easington Mine (Diesel Vehicles) Special Regulations 1962</td>
<td>S.I. 1962/1676</td>
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<tr>
<td>The Rufford Mine (Diesel Vehicles) Special Regulations 1962</td>
<td>S.I. 1962/2059</td>
<td>Regulations 4 to 6</td>
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<td>The Wharncliffe Woodmoor 4</td>
<td>S.I. 1962/2193</td>
<td>Regulations 4 to 6</td>
</tr>
</tbody>
</table>

(a) S.I. 2006/2183.
<table>
<thead>
<tr>
<th>Location of Mine</th>
<th>Regulations and Dates</th>
</tr>
</thead>
<tbody>
<tr>
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<td>S.I. 1962/2512, Regulations 4 to 6</td>
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<tr>
<td>The Dawdon Mine (Diesel Vehicles)</td>
<td>S.I. 1963/118, Regulations 4 to 6</td>
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<td>The Thoresby Mine (Diesel Vehicles)</td>
<td>S.I. 1963/825, Regulations 4 to 6</td>
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<tr>
<td>The Westoe Mine (Diesel Vehicles)</td>
<td>S.I. 1963/1096, Regulations 4 to 6</td>
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<tr>
<td>The Silverwood Mine (Diesel Vehicles)</td>
<td>S.I. 1963/1618, Regulations 4 to 6</td>
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<tr>
<td>The Prince of Wales Mine (Diesel Vehicles)</td>
<td>S.I. 1964/539, Regulations 4 to 6</td>
</tr>
<tr>
<td>The Newbiggin Mine (Diesel Vehicles)</td>
<td>S.I. 1964/899, Regulations 5 to 7</td>
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<tr>
<td>The Cwmgwili Mine (Diesel Vehicles)</td>
<td>S.I. 1964/1225, Regulations 4 to 6</td>
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<tr>
<td>The Wearmouth Mine (Diesel Vehicles)</td>
<td>S.I. 1964/1476, Regulations 4 to 6</td>
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<tr>
<td>The South Crofty Mine (Locomotives)</td>
<td>S.I. 1965/759, Regulations 4 to 6</td>
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<td>The Bevercotes Mine (Diesel Vehicles)</td>
<td>S.I. 1965/1194, Regulations 4 to 6</td>
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<td>The Sallet Hole Mine (Storage Battery Locomotives)</td>
<td>S.I. 1966/1325, Regulations 4 to 8</td>
</tr>
<tr>
<td>The Ellington Mine (Diesel Vehicles and Storage Battery Vehicles)</td>
<td>S.I. 1967/956, Regulations 4 to 7</td>
</tr>
<tr>
<td>The Groverake Mine (Storage Battery Locomotives)</td>
<td>S.I. 1967/1545, Regulations 4 to 8</td>
</tr>
<tr>
<td>The Fauld Mine (Diesel Vehicles)</td>
<td>S.I. 1968/1295, Regulations 5 to 7</td>
</tr>
<tr>
<td>The Prince of Wales Mine (Captive Rail Diesel Locomotives)</td>
<td>S.I. 1969/1377, Regulation 4</td>
</tr>
<tr>
<td>The Winsford Rock Salt Mine (Diesel Vehicles)</td>
<td>S.I. 1971/50, Regulations 4 to 7</td>
</tr>
</tbody>
</table>
### Part 2: Regulations made under the Mines and Quarries Act 1954 and the 1974 Act

<table>
<thead>
<tr>
<th>Title</th>
<th>Reference</th>
<th>Extent of Disapplication</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Rixey Park Mine (Storage Battery Locomotives) Special Regulations 1974</td>
<td>S.I. 1974/1866</td>
<td>Regulations 4 to 8</td>
</tr>
</tbody>
</table>

### Part 3: Regulations made under the 1974 Act

<table>
<thead>
<tr>
<th>Title</th>
<th>Reference</th>
<th>Extent of Disapplication</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Markham Mine (Diesel Vehicles) Regulations 1976</td>
<td>S.I. 1976/1734</td>
<td>Regulations 4 to 6</td>
</tr>
<tr>
<td>The Sallet Hole Nos 1 and 2 Mines (Diesel Vehicles) Regulations 1978</td>
<td>S.I. 1978/761</td>
<td>Regulations 5 to 7</td>
</tr>
<tr>
<td>The Boulby Mine (Diesel Vehicles) Regulations 1979</td>
<td>S.I. 1979/1532</td>
<td>Regulations 5 to 8</td>
</tr>
<tr>
<td>The Sallet Hole No. 2 Mine (Storage Battery Locomotives) Special Regulations 1980</td>
<td>S.I. 1980/1203</td>
<td>Regulations 4 to 9</td>
</tr>
<tr>
<td>The Harworth Mine (Cable Reel Load-Haul-Dump Vehicles) Regulations 1980</td>
<td>S.I. 1980/1474</td>
<td>Regulations 4 to 6</td>
</tr>
<tr>
<td>The Point of Ayr Mine (Diesel Vehicles) Regulations 1980</td>
<td>S.I. 1980/1705</td>
<td>Regulations 4 to 6</td>
</tr>
</tbody>
</table>
EXPLANATORY NOTE

(This note is not part of the Regulations)


The Machinery Directive is a “New Approach” directive. New Approach directives aim to remove technical barriers to trade by harmonising national health and safety provisions in respect of particular types of product in so far as they apply to such products when they are first placed on the market or put into service in the EEA. Products which comply with their requirements are “CE” marked and can be placed on the market and put into service throughout the EEA.

The scope of the Regulations is set out in Part 1 (which also deals with other preliminary matters, such as commencement) and Part 2. In particular, regulations 4(2) and 5 set out the types of product which constitute “machinery” and “partly completed machinery” which are subject to the Regulations.

Part 3 sets out the key obligations on those who place machinery or partly completed machinery on the market or put it into service (referred to in the Directive as “manufacturers or their authorised representatives” and in the Regulations as “responsible persons”). These obligations include ensuring the safety of products (by reference to the essential health and safety requirements set out in Part 1 of Schedule 2 (“Annex I”), following a “conformity assessment procedure” (regulations 10 to 12) and documenting their compliance with the requirements of the Regulations in various ways (notably by drawing up an “EC declaration of conformity” and affixing the CE marking to the product).

Part 4 makes further provision about CE marking. Part 5 is concerned with the activities of “notified bodies”, whose function is to assess the conformity of products with the Regulations. Part 6 makes provision about enforcement.


An Impact Assessment (IA) in respect of these Regulations is available and a copy can be obtained from the Department for Business, Enterprise & Regulatory Reform. As these Regulations transpose the Machinery Directive, a transposition note (TN) setting out how the Government will transpose the Directive into UK law has been prepared. Copies of the IA and TN are available from the Business Group, Department for Business, Enterprise & Regulatory Reform, 1 Victoria Street, London SW1H 0ET. Copies of these documents have been placed in the libraries of both Houses of Parliament.
Commission Guidance (by Q & A) on some specific issues of interpretation

Q1: Is there a transitional period for application of Directive 2006/42/EC?

**Answer:** In general, there is no transition period, in the sense of a period during which both the current Machinery Directive and the new Machinery Directive are applicable (with one exception: there is a transition period until 29th June 2011 for the particular case of portable cartridge-operated fixing and other impact machinery).

However there is a period of adaptation, since the provisions of the Directive 2006/42/EC become applicable on 29th December 2009. During this period, all of the stakeholders concerned will be able to take the necessary steps to ensure a smooth transition from the current Directive to the new Directive.

Q2: Can manufacturers anticipate application of the new Machinery Directive?

**Answer:** Yes and no. Manufacturers can and should anticipate application of Directive 2006/42/EC from a practical and technical point of view, however, from a formal, legal point of view; the Directive cannot be applied before 29th December 2009:

- from the practical and technical point of view, manufacturers are encouraged to review their products without delay and adapt them as necessary to take account of the requirements of the new Directive. While machinery placed on the market before 29th December 2009 must continue to comply with Directive 98/37/EC, it can be assumed that a product that complies with the essential requirements of the new Machinery Directive continues to comply with the current Directive.

- from the formal, legal point of view, machinery can only be placed on the market with reference to Directive 2006/42/EC as from 29th December 2009.

Q3: When shall a manufacturer establish an EC Declaration of conformity according to Directive 2006/42/EC?

**Answer:** A manufacturer shall establish an EC Declaration of conformity according to Directive 2006/42/EC for products first placed on the market as from 29th December 2009.

In cases where the manufacturer cannot be certain on what date individual products will be first placed on the market, provided the products concerned comply with both the current and the new Directives, he may establish an EC Declaration of conformity referring to Directive 98/37/EC and Directive 2006/42/EC. The reference to Directive 98/37/EC should be removed from the EC Declaration of conformity after the 29th December 2009.

Q4: Can the current harmonised standards be used to comply with Directive 2006/42/EC?

**Answer:** Since there have been some modifications to the essential health and safety requirements set out in Annex I, it cannot be assumed that the current harmonised standards comply fully with Directive 2006/42/EC.
The European Commission is issuing a mandate to CEN and Cenelec to develop the necessary new standards and ensure that the current standards are checked against Directive 2006/42/EC and adapted as necessary. Furthermore, all harmonised standards must include a reference to the new Directive. The Commission intends to publish a list of harmonised standards supporting Directive 2006/42/EC before the Directive becomes applicable.

Q5: When will manufacturers be able to use the new full quality assurance procedure for Annex IV machinery?

Answer: The Member States will first have to assess, appoint and notify Notified Bodies for the new full quality assurance procedure set out in Annex X of the new Directive. This can be done as soon as Directive 2006/42/EC has been transposed into national law. As soon as Bodies have been notified for this procedure, they will be able to carry out the necessary audits and inspections and issue approvals of manufacturers’ full quality assurance systems. However, products cannot be placed on the market on the basis of such approvals until Directive 2006/42/EC becomes applicable on 29th December 2009.

Q6: Will the existing Notified Bodies be able to carry out EC type-examinations according to Directive 2006/42/EC?

Answer: Bodies that are notified to carry out EC type-examinations under Directive 98/37/EC will be able to continue to carry out EC type-examinations under Directive 2006/42/EC, providing their notification covers the product categories concerned. For product categories included in Annex IV of Directive 2006/42/EC that are not listed in Annex IV of Directive 98/37/EC, the Member States will have to notify new Bodies or extend the scope of the notification of existing ones.

Q7: Will EC type-examination certificates established according to Directive 98/37/EC remain valid for Directive 2006/42/EC?

Answer: Since there have been some modifications to the essential health and safety requirements set out in Annex I, it cannot be assumed that EC type-examination certificates issued according to Directive 98/37/EC remain valid for Directive 2006/42/EC. Furthermore, such certificates must be updated to refer to Directive 2006/42/EC. Notified Bodies will thus have to review existing EC type-examination certificates to ensure that they remain valid in light of the requirements of the new Directive and update them to refer to Directive 2006/42/EC. Manufacturers are encouraged to request this review without delay in order to avoid a bottleneck in the months preceding December 2009. Since Directive 2006/42/EC requires EC type-examination certificates to be reviewed every 5 years (see Annex IX, section 9.3), the 5-year period for existing certificates can be counted from the date on which they have been updated according to Directive 2006/42/EC.
Q8: What will happen to products certified according to one of the procedures set out in Article 8 (2) (c) of Directive 98/37/EC (Receipt of technical file or Certificate of adequacy to harmonised standards)?

Answer: The procedures set out in Article 8 (2) (c) of Directive 98/37/EC will no longer exist under Directive 2006/42/EC. As from 29th December 2009, manufacturers of products placed on the market on the basis of these procedures will therefore have to apply one of the procedures set out in Article 12 (3) and (4) of Directive 2006/42/EC.

For products manufactured in accordance with harmonised standards that cover all the relevant health and safety requirements, the manufacturer will be able to certify the conformity of the product himself according to the procedure set out in Article 12 (3) (a) of the Directive.
What is the problem under consideration? Why is government intervention necessary?
There are two main problems under consideration. The first relates to the placing of machinery on the EU market, and the second relates to the appropriate level of health and safety protection for those using, or coming into contact with, machinery. Government intervention is necessary to establish the legal framework for a 'single market' in machinery, and it is necessary because the 'full' social costs of injuries are estimated to exceed the private costs and this can lead to health and safety protection which is too low from the viewpoint of society as a whole.

What are the policy objectives and the intended effects?
The policy objective is to transpose the new European Machinery Directive to protect and promote the 'single market' in machinery, and to provide the appropriate level of health and safety protection for those using, or coming into contact with, machinery. The intended effects are that manufacturers and/or importers of machinery only place machinery on the EU market which meets relevant essential health and safety requirements.

What policy options have been considered? Please justify any preferred option.
The main policy options considered were those in negotiation of the new European Machinery Directive. The Government supports the EU's 'New Approach' to regulation on which the new Directive is based, and negotiated the new Directive to achieve improvements over and above the existing Directive, and a modernisation of the existing Directive. The new Machinery Directive is a harmonisation measure based on Article 95 of the EC Treaty. It allows the UK some latitude regarding procedural matters, such as details of enforcement, but gives few options as regards its substantive requirements.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?
The policy will be reviewed by BERR three years after the provisions of the draft SI come into effect.

Ministerial Sign-off For consultation stage Impact Assessments:
I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister:

.................................................................................................................. Date:
## Summary: Analysis & Evidence

<table>
<thead>
<tr>
<th>Policy Option: Transposition of Machinery Dir</th>
<th>Description: UK Regulations aim to transpose the new European Machinery Directive.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ANNUAL COSTS</strong></td>
<td>Description and scale of key monetised costs by ‘main affected groups’ Costs will be incurred by manufacturers and professional importers of machinery placing machinery on the EU market. Main costs are familiarisation and training costs, with some design and build costs.</td>
</tr>
<tr>
<td><strong>One-off (Transition)</strong></td>
<td>Yrs</td>
</tr>
<tr>
<td><strong>Average Annual Cost</strong></td>
<td>(excluding one-off)</td>
</tr>
<tr>
<td><strong>Total Cost (PV)</strong></td>
<td>£ 16 million</td>
</tr>
<tr>
<td><strong>Other key non-monetised costs by ‘main affected groups’</strong></td>
<td></td>
</tr>
<tr>
<td><strong>ANNUAL BENEFITS</strong></td>
<td>Description and scale of key monetised benefits by ‘main affected groups’ Protection and enhancement of 'single market' in machinery should lead to greater competition and innovation, and removal of non-compliant machinery, to benefit of UK businesses and cons consumers. Benefits to UK users, and those coming into contact with machinery from enhanced health and safety protection.</td>
</tr>
<tr>
<td><strong>One-off</strong></td>
<td>Yrs</td>
</tr>
<tr>
<td><strong>Average Annual Benefit</strong></td>
<td>(excluding one-off)</td>
</tr>
<tr>
<td><strong>Total Benefit (PV)</strong></td>
<td>£ 25-83 million</td>
</tr>
<tr>
<td><strong>Other key non-monetised benefits by ‘main affected groups’</strong></td>
<td>Protection of environment and enhancement of animal welfare, where machinery is involved or where animals come into contact with machinery.</td>
</tr>
</tbody>
</table>

**Key Assumptions/Sensitivities/Risks** Existing Machinery Directive has had 10-20 per cent positive impact on 'machinery sector' and on health and safety; New Directive is up to 10 per cent improvement over existing Directive.

### Price Base Year 2007 | Time Period Years 10 | Net Benefit Range (NPV) £ 9-67 million | NET BENEFIT (NPV Best estimate) £ 9-67 million
---|---|---|---
What is the geographic coverage of the policy/option? | UK |
On what date will the policy be implemented? | 29/12/2009 |
Which organisation(s) will enforce the policy? | HSE/ORR/LAs |
What is the total annual cost of enforcement for these organisations? | £ No additional |
Does enforcement comply with Hampton principles? | Yes |
Will implementation go beyond minimum EU requirements? | No |
What is the value of the proposed offsetting measure per year? | £ None |
What is the value of changes in greenhouse gas emissions? | £ Zero |
Will the proposal have a significant impact on competition? | No |
Annual cost (£-£) per organisation (excluding one-off) | Micro 108 | Small 108 | Medium 108 | Large 108 |
Are any of these organisations exempt? | No | No | N/A | N/A |
**Impact on Admin Burdens Baseline (2005 Prices)** | (Increase - Decrease) | | | |
| Increase of | £ 0.3 mill | Decrease of | £ | Net Impact | £ 0.3 million |

**Key:** Annual costs and benefits: Constant Prices (Net) Present Value
Purpose and intended effect

Objective


2. Directive 2006/42/EC updates and replaces the existing European Directive on Machinery (Directive 98/37/EC). BERR’s draft SI aims to repeal a number of existing SIs implementing the existing Machinery Directive in the UK, revoking three whole separate Regulations, and two Regulations in part.²

3. The new Machinery Directive has, like the existing Machinery Directive, the following main objectives;

- To ensure the free movement of machinery falling within its scope across the member States of the European Union (an ‘internal market objective’).

- To provide for the appropriate level of health and safety for persons in the European Union using and coming into contact with machinery (a ‘health and safety objective’).

- To provide for the appropriate level of environmental protection, and protection of animals, in situations where machinery is involved (an ‘environmental and animal protection objective’).

4. BERR’s draft SI aims to implement the new Machinery Directive in the UK to achieve these objectives.

Background

5. Directive 2006/42/EC, the new Machinery Directive, aims to rationalise and modernise the existing Machinery Directive (98/37/EC). It aims to bring greater clarity to the legislative framework applying to the production and use of machinery. This is in terms of, for example, re-drafting the scope and applications of machinery covered by the Directive, and in terms of making a clearer distinction between the Machinery Directive and other relevant legislation, such as the Lifts Directive and the Low Voltage Directive (LVD).

6. The Machinery Directive is based on the principles of the European Union’s ‘New Approach’.

7. The ‘New Approach' aims to maximise the free movement of goods within the internal market of the European Union by removing barriers to trade resulting from the adoption of diverging national technical standards and regulations.

¹ This Directive also amends Directive 95/16/EC which is concerned with Lifts.

² These are referenced in Schedule 1 of the draft SI.
8. The ‘New Approach’ introduces ‘harmonised legislation’ limited to the essential requirements that products must meet to be placed on the EU market, and to benefit from free movement within the Community. ‘New Approach’ Directives are based on Article 95 of the EC Treaty.

9. The first Directive in relation to machinery entered into force on 1 January 1993. This Directive has been amended three times and was consolidated into the existing Directive on machinery (Directive 98/37/EC) which came into force in August 1998.


11. The resulting new Machinery Directive was adopted on 29 June 2006, and member States are required to transpose its requirements into national law by 29 June 2008, with the provisions of the Directive being applicable in member States from 29 December 2009.

**Rationale for Government Intervention**

12. Potential barriers to trade caused by adoption of diverging national technical standards and regulations are often considered in terms of, so-called, ‘non-tariff trade barriers’. In attempting to remove such barriers, to obtain the benefits from trade liberalisation, Government plays an important role in establishing the legislative framework in which businesses and consumers can conduct their transactions on a ‘level playing field’ within transparent and predictable rules.

13. In terms of health and safety, the ‘full’ economic, or social, costs of injuries are estimated generally to exceed the private costs. The costs of health and safety impacts are often considered in terms of ‘direct’ costs such as the use of health care resources, and ‘indirect’ costs such as impacts on the quality of life. The fact that indirect costs may not be taken into account by, for example, businesses when they establish their own health and safety standards means that from the viewpoint of society, these health and safety standards may be too low. Government may be able to establish the appropriate levels of health and safety for society as a whole which more closely reflects the ‘full’ costs and benefits of health and safety impacts.

**Consultation**

14. BERR played an active role in negotiations for the new Machinery Directive at European level. In this role BERR was supported by the UK’s Health and Safety Executive (HSE).

15. BERR maintained links with key representatives of the main industrial sectors affected by the Machinery Directive throughout the negotiation of the new Directive. This partial IA forms part of BERR’s public consultation on the draft Regulations to implement the new Machinery Directive in the UK.

**Options**

16. During negotiations on the new Machinery Directive the UK had three main options. These were: to seek to get the existing Machinery Directive removed from the EU statute book; to seek to obtain no revisions to the existing Machinery Directive and its amendments; or to seek revisions to the existing Machinery Directive.

17. The UK Government supports the aims of the Machinery Directive and the principles of the ‘New Approach’ which underpin the Machinery Directive, and thus the first of these options is

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3 The removal of such ‘non-tariff trade barriers’ can result in greater competition and increased innovation for the benefit of both business and consumers alike.
not considered further in this partial IA. This partial IA outlines the costs and benefits of the new Machinery Directive compared to the existing Machinery Directive.

18. The new Machinery Directive is a harmonisation measure based on Article 95 of the Treaty establishing the community. It allows member States some latitude as regards procedural matters such as the details of enforcement at national level, but gives them very few options as regards the substantive requirements to be imposed on businesses: it does not permit member States to impose more stringent health and safety requirements for machinery than are provided for in the Directive and it has very few derogation provisions.

Costs and Benefits

19. The new Machinery Directive takes its scope from the existing Machinery Directive and applies to the following products:

(a) Machinery;
(b) Interchangeable equipment;
(c) Safety components placed separately on the market;\(^4\)
(d) Lifting accessories;
(e) Chains, ropes and webbing;
(f) Removable mechanical transmission devices;
(g) Partly completed machinery.

20. The range of products outside of the scope of the new Machinery Directive, largely because they are covered by other legislation, includes:

(a) Specific equipment for fairgrounds/amusement parks;
(b) Machinery specifically for nuclear purposes;
(c) Weapons, including firearms;
(d) Agriculture and forestry tractors;
(e) Motor vehicles and their trailers;
(f) Aeroplanes, boats and trains;
(g) Machinery specifically for military or police purposes;
(h) Mine winding gear;
(i) Electrical and electronic products falling under the Low Voltage Directive (LVD);
(j) High voltage switch gear, control gear, and transformers.

21. Though the new Machinery Directive takes its scope from the existing Machinery Directive it applies its requirements to two additional types of machinery. These are:

(a) Construction site hoists intended for lifting persons or persons and goods;\(^5\)
(b) Portable cartridge-operated fixing devices.\(^6\)

22. In addition, there are some small changes in scope caused by a revised definition in relation to the Low Voltage Directive (LVD),\(^7\) and a clearer demarcation between the Machinery

\(^4\) Safety components intended to be used as spare parts to replace identical components of existing machinery are outside the scope of the Directive.

\(^5\) As there is no specific legislation in this area currently with regard to their being placed on the market.

\(^6\) Such as fixing tools, stunning pistols, and marking guns, for which there is no specific legislation with regard to their being placed on the market.

\(^7\) This relates to xx and is reflected in Regulation xx of the DTI’s SI.
Directive and the Lifts Directive. The latter is likely to result in more lifting platforms and other ‘slow’ lifts being covered by the Machinery Directive.\(^8\) The scope of the new Machinery Directive is reflected in BERR’s draft SI.

23. The new Machinery Directive, and therefore BERR’s draft SI, requires manufacturers of machinery (or their ‘authorised representatives’) to undertake the following activities before they can place machinery on the European market or put it into service:

(i) Ensure the machinery satisfies relevant essential health and safety requirements;

(ii) Ensure a technical file is made available, demonstrating that the design, manufacture, and operation of machinery complies with certain essential health and safety requirements;

(iii) Provide necessary information, relating to the machinery, such as instructions for use;

(iv) Carry out appropriate procedures for assessing conformity, draw-up a declaration of conformity, and ensure this accompanies the machinery;

(v) Affix a CE marking to the machinery.

24. In addition, before placing ‘partly completed machinery’ on the market, a manufacturer (or his ‘authorised representative’) is required to: prepare technical documentation covering the design, manufacture, and operation of the partly completed machinery; prepare and provide assembly instructions for the partly completed machinery; and provide a ‘declaration of incorporation’ to show that partly completed machinery conforms to the necessary essential requirements.

25. The requirements on manufacturers (or their ‘authorised representatives’) in relation to machinery contained within the new Machinery Directive are broadly the same as those contained in the existing Machinery Directive, except where the two new types of machinery have been bought into scope, and where there are more specific requirements for partly completed machinery.\(^9\) These Directive requirements are reflected in BERR’s draft SI.

### Sectors and groups affected

26. Because of the nature and scope of the Machinery Directive itself, it is difficult to estimate with precision the number of businesses, users and consumers that will be affected by BERR’s draft SI. The Machinery Directive covers a vast array of different types of ‘machinery’. The European Commission’s Explanatory Memorandum to the new Machinery Directive\(^10\) uses statistics from the engineering sector to proxy those who could be impacted by the new Directive.

27. BERR’s draft SI will affect, at least, the following sectors and groups:

- Businesses falling under the Standard Industrial Code (SIC) DK 29, i.e. ‘Manufacture of Machinery and Equipment not elsewhere classified’;

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\(^8\) The Machinery Directive amends the Lifts Directive such that lifts that move slower than 0.15 metres per second are to be covered by the Machinery Directive and not the Lifts Directive.

\(^9\) In terms of its health and safety requirements, ‘partly completed machinery’ needs to be treated as if it were ‘complete’ machinery.


• Professional Importers of machinery into the UK;

• Users of machinery;

• Animals coming into contact with machinery.

28. Data from the Office of National Statistics (ONS) for category DK (SIC Code 29) “Manufacture of Machinery and Equipment not elsewhere classified” reports that in 2005, 12,876 enterprises operated in this sector in the UK, having a turnover in excess of £34 billion and employing some 289,000 people. Within category DL 30 and category DM 34 not all enterprises will produce machinery or machinery that is within the scope of the new Machinery Directive. We can take data from DK 29 as an estimate for the number of businesses that could be affected by the draft SI, though even some businesses in this category will be producing machinery that is outside the scope of the new Machinery Directive.

29. It is unclear how many people use, or come into contact with, machinery on a day-to-day basis in the UK, and it is also unclear how many animals come into contact with machinery.

Benefits

30. The benefits of BERR’s draft SI to transpose the new Machinery Directive into UK law are difficult to quantify. The Machinery Directive covers a vast array of machinery, used in a large number of sectors and across a range of applications.

31. In general terms, the benefits of the draft SI can be seen in terms of the following:

• positive contributions to the effective operation of the European Union ‘Internal Market’;

• positive contributions to health and safety for those using, or coming into contact with, machinery;

• positive contributions to improvements in animal welfare and protection of the environment where machinery is involved.

Internal Market benefits

32. As noted above, the ‘New Approach’ of the European Union aims to achieve technical harmonisation and standardisation across a range of product sectors to promote the free movement of goods across the European ‘Internal Market’. The adoption of diverging national technical standards and regulations can cause concern because these can become a barrier to trade – a so-called ‘non-tariff trade barrier’. Removal of such non-tariff trade barriers can have positive impacts on efficiency, innovation, and growth.

33. The existing Machinery Directive has been in operation for a number of years and will have already produced the main positive impacts from ‘liberalisation’ of the market for machinery across Europe. It is not straightforward to estimate the benefits that may accrue to the UK from BERR’s draft SI, as a consequence of the removal of any additional barriers to trade involving machinery.
34. The Commission’s *Explanatory Memorandum (EM)* to the new Directive says that “..carrying out a proper cost-benefit analysis..of the Directive for every specific situation is virtually impossible, given the variety of possible situations.”

But, the EM also says that “..those consulted agree that the revision of the Directive has improved a number of points whose interpretation has caused uncertainty.”

35. An example of this reduction in uncertainty concerns the relationship between the Machinery and Lifts Directives. In principle ‘lifts’ can be considered to be ‘machinery’, but because most passenger lifts are designed to move people at speed they need to satisfy more specialised essential safety requirements. They were therefore excluded from the Machinery Directive and accommodated in their own Directive, the Lifts Directive. The dividing line between the two Directives was widely believed to give too much scope for manufacturers to claim that certain ‘borderline’ products, which on the face of it should fall under the more tailored requirements of the Lifts Directive, actually fell under the Machinery Directive. The new Machinery Directive introduces new criteria, including, crucially a speed limit, that enables a clearer and more rational division to be made between the respective scopes of the two Directives.

36. As well as this, and other, contributions to reductions in uncertainty, the new Machinery Directive also modernises and simplifies the existing Directive. Thus the new Directive can be seen, in this context, as an improvement over the existing Directive, but it is difficult to quantify the extent of this improvement.

37. The new Machinery Directive will impact on trade in machinery across Europe, affecting all member States that export and import machinery. In terms of those exporting machinery into the EU, this includes non-EU countries, and so it is difficult to estimate the benefits to the UK specifically, of any growth in trade in machinery following introduction of the new Machinery Directive.

38. In addition, a further reduction in non-tariff barriers in machinery, as it leads to increased competition, may have positive impacts on the quality of machinery, and also lead to reductions in prices, which would be of benefit to UK businesses importing machinery, and subsequently to UK consumers purchasing goods and services from the use of machinery. But again, such benefits are difficult to quantify.

39. Below we provide a range of estimates, which, though somewhat crude, may provide an indication of the potential ‘internal market’ benefits from BERR’s draft SI.

40. One method of estimation is to view the new Machinery Directive in the context of the European Union’s Internal Market programme. A paper by the European Commission attempts to estimate the economic gains to the European Union resulting from the Internal Market programme by using a model to simulate the competition and innovation effects of the programme.

41. The Commission’s paper estimates that in 2006 the internal market programme had a positive effect on European GDP in the region of 1.8 per cent, and that this was equivalent to 180 billion Euros in 2002 prices.

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11 Explanatory Memorandum, COM 2000 (899) final (page 12).


42. The UK represents around one-sixth of the European economy. Manufacturing represents around 15 per cent of UK GDP, and machinery is estimated to represent around 8 per cent of manufacturing. Up-rating the Commission’s estimate to today’s prices, and using the percentage splits above implies that the Internal Market programme may have had a positive impact on the machinery sector of the UK in the region of some £270 million in 2006.

43. The Internal Market programme consists of a wide range of policies and initiatives of which the ‘New Approach’ and the ‘Machinery Directive’ are only one part. Though the Machinery Directive is an important Directive it is unlikely in itself to provide a significant proportion of the total gains of the Internal Market programme. If it represented some 10-20 per cent of the impact of the total programme for the machinery sector it could have been responsible for benefits in the region of £27 million to £54 million to the ‘machinery sector’ of the UK in 2006.

44. The new Machinery Directive updates and simplifies the existing Directive, and in this context can be seen as an improvement over the existing Directive, but the extent of this improvement is difficult to quantify.

45. One of the main areas of improvement in the new Directive is the simplified conformity assessment procedures for certain machines considered of higher risk, and listed in Annex IV of the Directive. Other areas of improvement include up-dated and clearer definitions of the scope of the Directive; the application of the Directive to ‘partly completed machinery’; and the relationship of the Directive to the Lifts Directive and the Low Voltage Directive.

46. An estimate for the extent of these improvements over and above the existing Directive in the region of up to 10 per cent may not be unreasonable. If this improvement resulted in similar levels of improvement in benefits to the ‘machinery sector’ this would imply an estimate of the internal market benefits of BERR’s draft SI to the ‘machinery sector’ of the UK in the region of up to £3 million to £7 million per annum over the period 2010-2019.

47. An alternative estimate can be based on estimates of the benefits that could be achieved by removing barriers to trade in services. A report by Copenhagen Economics for the European Commission on the potential benefits resulting from the Services Directive estimated that the Services Directive could lead to a reduction in non-tariff barriers in services of over 50 per cent, with a subsequent positive impact on value added in the services sector of just over 1 per cent.

48. One of the main aims of the existing Machinery Directive was the reduction in barriers to trade in machinery. However, these barriers were unlikely to be as high as those that potentially exist in services because, prior to the first Machinery Directive, there was a well-established international market in machinery.

49. If we assume that the first Machinery Directive had around half of the expected impact of the Services Directive, then based on the ‘machinery sector’ share of UK GDP (of just over 1 per cent) this would imply that the existing Directive may have contributed in the region of £86 million to ‘machinery’ value added. If the new Directive brings additional benefits upwards of a further 10 per cent, this would imply benefits from the draft SI in the region of £9 million to £12 million per annum over the period 2010-2019.

50. A further estimate can be made by comparing possible gains from increasing compliant activity as a proportion of total activity in the machinery sector, compared to activity in the manufacturing sector generally. This estimate is based on estimates of the relative average

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15 Calculated as UK GDP of around £1.3 trillion multiplied by 15 per cent, multiplied by 8 per cent, with 0.5 per cent of value added in machinery being attributable to the existing Machinery Directive.
rate of return achievable from using resources in the machinery sector, compared to the average rate of return available from the next best alternative use of these resources, assumed here to be manufacturing generally.

51. If we assume that the existing Machinery Directive has contributed to reducing the proportion of non-compliant activity by, for example, up to 10 per cent then based on figures for EU ‘consumption’ of mechanical engineering equipment this would imply that the existing Directive has increased compliant activity across Europe by some £25 billion.\(^{16}\) The average rate of return in UK manufacturing is estimated at around 7 per cent currently, and, because of its potential greater risk and use of technology, we could expect average returns in mechanical engineering to be slightly greater than that in manufacturing generally, say up to 5 per cent higher, and so producing an average return of under 7.5 per cent.

52. If we assume that the new Directive will bring an additional 10 per cent improvement over the existing Directive this would imply benefits from the draft SI in the region of £10 million to £12 million per annum over the period 2010-2019.\(^{17}\)

53. All of the above estimates are rather crude and rely on a significant number of assumptions being made. Thus they can only be viewed as being indicative estimates of the possible gains from the draft SI transposing the new Machinery Directive into UK law. These indicative estimates are summarised in Table 1.

<p>| Table 1: An Estimate of the Internal Market Benefits from BERR’s draft SI (£ million) |</p>
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Health and Safety Benefits

54. One of the objectives of the Machinery Directive is to “...lay down the essential health and safety requirements in relation to design and manufacture in order to improve the safety of machinery placed on the market” (Recital 28 of the Machinery Directive).

55. The use of machinery in the work place has risks which can result in fatalities, major injuries, and minor injuries. The Health and Safety Executive (HSE) collects and publishes accident statistics resulting from contact with moving machinery or material being machined. These statistics are categorised by three types: fatal injuries; non-fatal major injuries (averaging greater than 3 months off work); and ‘over 3 days’ off work injuries.

56. In estimating the health and safety benefits resulting from BERR’s draft SI a number of steps need to be followed. First, an estimate of the impact of the existing Machinery Directive on the number of injuries resulting from the use of machinery needs to be made; secondly, an estimate of the additional impact of the new Machinery Directive on these injuries needs to be made; thirdly, these additional impacts need to be valued using estimates from established

\(^{16}\) Figures for EU ‘consumption’ of mechanical engineering suggest that the market is worth over 350 billion euro across Europe. One of the aims of the Machinery Directive is to ensure that all machinery sold in the EU conforms to essential health and safety requirements, and machinery that does not conform to such requirements is denied access to the market. Of the total market we assume that some proportion of this was taken by non-compliant machinery prior to the Machinery Directive.

\(^{17}\) Calculated as 10 per cent increase in compliant activity over that attributed to existing Directive, and that activity earning a return of around 7.4 per cent compared to a return of 7 per cent in manufacturing generally.
methodologies; and fourthly, these values need to be discounted to present values when they occur over time.

57. With regard to fatal injuries, HSE data shows that for employees and the self-employed coming into contact with moving machinery (across all sectors of the economy), the number of fatalities has fallen from 34 in 1988/89 to 23 in 2005/06. However, the nature of injuries as accidents means that this fall in fatalities over time has not been smooth.

58. Accidents by their vary nature can have a large random element, and accidents involving machinery are determined by a number of factors. These include ‘general’ factors, such as the level of activity in the economy (affecting the level of use of machinery), and technological developments (affecting levels of exposure to machinery), and ‘individual’ effects, such as the conditions of maintenance and use of machinery, and the qualities of the person using a specific type of machinery. This means it is difficult to isolate the specific impacts of the Machinery Directive on injuries.

59. The existing Machinery Directive came into force across Europe in 1998. However, this was largely a consolidation of existing European legislation on machinery first introduced in 1989, and transposed by UK Regulations coming into force in 1993. The 1998 Machinery Directive, being a consolidation, did not require new and specific UK legislation. This means that the effects of the Machinery Directive on UK trends in health and safety should be considered by comparing events prior to 1993 with those after 1993.

60. HSE data for fatal injuries from coming into contact with moving machinery, across all sectors of the economy, shows that between 1988/89 and 1993/94 fatal injuries averaged some 27 per annum. From 1995/96 to 2005/06 fatal injuries have averaged almost 19 per annum.

61. It is difficult to attribute all of this fall in the average number of fatalities to the Machinery Directive. Indeed, given the range of factors that could impact on the number of injuries from the use of machinery, the Machinery Directive is likely to contribute only a proportion of any reduction. However, the essential requirements of the Machinery Directive will have had some positive impact in terms of contributing to reducing the number of fatalities resulting from contact with, or use of, machinery.

62. If we assume that the existing Machinery Directive contributed in the region of 10 per cent to 20 per cent of the reduction in the average number of fatalities from contact with machinery, then this would imply that the Machinery Directive led to a reduction in the average number of fatalities of just under 1-2 per annum.

63. The new Machinery Directive updates the existing Directive to increase its clarity and simplify its text. Increased clarity and simplification is likely to increase understanding of the Machinery Directive and have subsequent positive impacts on reducing injuries where machinery is involved.

64. However, though the new Directive can be seen as an improvement over the existing Directive, in this context, the extent of this improvement is again difficult to quantify. If we assume again that the new Directive is an improvement in the region of up to 10 per cent over the existing Directive (as we did to estimate the Single Market benefits above), and this has subsequent positive impacts on the effectiveness of the Directive in terms of health and safety, then the possible reduction in the average number of fatalities resulting from the new Directive could be in the region of 0.1-0.2 per annum.
65. The Department for Transport (DfT) estimates the average cost of a fatal injury from a road accident in the region of £1.43 million.\textsuperscript{18} Up-rating this figure to 2007\textsuperscript{19} and applying it to the number of fatalities that could be avoided as estimated above, enables an estimate to be made of the value of the number of fatalities that could be avoided in the UK as a consequence of BERR’s draft SI.\textsuperscript{20}

66. HSE data is also available for non-fatal injuries. The two main categories of injury here are, “major injuries” averaging greater than 3 months off work, and “>3 day injuries”, averaging more than 3 days off work.

67. Between 1988/89 and 1993/94 ‘major injuries’ from coming into contact with moving machinery averaged some 1,700 per annum. Since then this figure has averaged some 1,500 per annum. Using the same methodology as that for fatal injuries outlined above, enables an estimate to be made of the possible benefits of the new Machinery Directive in terms of reducing the average number of ‘major’ injuries per annum. This estimate is in the range of, on average, 2 to 4 accidents per annum.

68. The HSE values the economic cost of a ‘major injury’ at £38,500 per injury currently, and using this number enables a monetary estimate to be made of the value of avoiding such injuries.\textsuperscript{21}

69. Between 1988/89 and 1993/94, ‘>3day injuries’ from coming into contact with moving machinery averaged just over 7,000 per annum. Since then this figure has averaged some 5,100 per annum. Using the same methodology as that for fatal and major injuries, enables an estimate to be made of the possible benefits of the new Machinery Directive in terms of reducing the average number of ‘>than 3 days’ injuries per annum. This estimate is in the range of an average between 22 to 44 accidents per annum.

70. The HSE values the economic cost of a >3day injury to be £5,500, and using this number enables a monetary estimate to be made of the value of avoiding such injuries.\textsuperscript{22}

71. In the estimates outlined above for possible injuries avoided, we have used data for injuries from coming into contact with moving machinery. However, there are injuries reported under other categories, which may also involve machinery, the major one of which is likely to be injuries as a consequence of falling from height, but also injuries from being struck by a moving

\textsuperscript{18} Highways Economic Note No. 1, January 2007. The DfT figure is for 2005 and is made up of estimates of the costs of lost output, medical and ambulance costs, and human costs. Human costs are the largest proportion of costs and represent “...pain, grief and suffering to the casualty, relatives and friends, and for, fatal casualties, the intrinsic loss of enjoyment of life over and above the consumption of goods and services.”

\textsuperscript{19} Based on growth in nominal GDP.

\textsuperscript{20} Though it is recognised that it is not necessarily appropriate to apply road accident figures to accidents involving machinery. Impacts on health can be seen as having a broadly constant utility value over time, regardless of changes in income. Future health benefits (or costs) can then be valued in today’s values by being discounted at a pure time preference rate. Within the Government’s current discount rate, pure time preference represents 1.5 per cent. An alternative method of estimating future health impacts is to calculate a rate of increase in their value over time and discount these at the ‘full’ discount rate (currently 3.5 per cent).

\textsuperscript{21} HSE Economic Analysis Unit (EAU) Appraisal Values, 13/04/07. The cost of a major injury consists of the costs of lost output, costs of medical treatment, investigation costs etc, and human costs. Human costs (reflecting pain, grief and suffering to the casualty, relatives, and friends) represent almost 50 per cent of total costs. We up-rate the HSE figure to today’s prices based on estimates of GDP growth.

\textsuperscript{22} The cost of a ‘>3 day’ injury consists of the costs of lost output, medical treatment etc, and human costs. Human costs (reflecting pain, grief and suffering to the casualty, relatives, and friends) represent almost 50 per cent of total costs. We up-rate the HSE figure using estimates of GDP growth.
or flying object, or from being struck by a moving vehicle. The data does not enable us to isolate instances where machinery may be involved.

72. Anecdotal evidence suggests that the actual number of injuries where machinery is involved may be up to 50 per cent higher than an estimate based on injuries from coming into contact with machinery alone. Using this, estimates of the monetary value of the health and safety benefits, i.e. from the possible avoidance of fatal, major, and ‘>3 day’ injuries, from BERRs draft SI are summarised in Table 2. It should be noted that given the number of assumptions that need to be made to arrive at these estimates, they should be seen as being indicative estimates, and also that these estimates do not include the avoidance of possible injuries from the use of machinery in non-workplace/industrial environments, such as the use of cordless power tools (CPTs) in households.

Table 2: An Estimate of the Value Health and Safety benefits in the UK from BERRs draft SI (£ million)

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Environmental and Animal Welfare Benefits

73. The new Machinery Directive, like the existing Machinery Directive, has as one of its aims, protection of the environment and protection of animal welfare where machinery is used, and where animals come into contact with machinery.

74. Government policy with respect to the health and welfare of animals is largely concerned with the prevention of outbreaks of disease which can have negative impacts on public health, animal welfare and the environment. However, the promotion of animal welfare goes beyond disease prevention.

75. The Government’s Animal Health and Welfare Strategy for Great Britain\(^{23}\) says that “...society cares about the welfare of animals as sentient creatures.” The Farm Animal Welfare Council has as part of its ‘Five Freedoms’, that animals should be free from discomfort, pain, injury, and fear and distress. As far as the new Machinery Directive promotes such ‘freedoms’ where animals come into contact with machinery, this should result in positive impacts on animal welfare and on the welfare of society generally, but these impacts are difficult to quantify given that there is no data available on injuries to animals from machinery.

Costs

76. The costs of BERR’s SI transposing the new Machinery Directive into UK law will fall largely on businesses designing and manufacturing machinery, though there will also be some costs to the public sector from market surveillance and conformity assessment activities. It is not clear that there will be any additional requirements on users of machinery as a result of the new Directive.

\((i)\) Familiarisation and Training Costs

77. There will be costs to businesses in terms of making themselves aware of the new SI and in terms of disseminating and applying the SI.

RIAs generally considered these costs in terms of so-called “familiarisation costs” which relate the length of time businesses need to read and understand new legislation, and in terms of “training costs” which relate to the length of time businesses need to disseminate and train managers and staff in new legislation. The following are some estimates from some RIAs:

- The HSE’s RIA for the ‘Control of Noise at Work Regulations’ (2006) estimates the costs of “familiarisation” as the costs of a manager taking one hour to familiarise him/herself with the Regulations, and values this time based on wage costs from the new earnings survey including a 30 per cent mark-up for non-wage labour costs. This is then multiplied by an estimate of the total number of businesses affected by the Regulations. These costs are taken as one-off costs incurred in the first year following the Regulations coming into force. The RIA estimates costs of providing information and training to workers by assuming that each worker spends 15 minutes per year “reading/listening to information”, valuing this time, and multiplying this by the estimated number of workers affected.

- The HSE’s RIA for the ‘Work at Height Regulations’ (2005) estimates “familiarisation costs” by assuming that “small businesses will require 2 hours and large businesses 4 hours to familiarise themselves with the proposed Regulations”. Here, a manager is assumed to earn an average of £20 an hour (including non-wage labour costs).

In terms of BERR’s draft SI transposing the new Machinery Directive, it is estimated that some 13,000 businesses could be affected. In line with other sectors of the economy, it is estimated that around 99 per cent of these businesses are small and medium-sized enterprises (SMEs).

BERR’s draft SI seeks to update and modernise existing UK legislation in relation to machinery. Thus industry is already aware of the nature, scope and aims of the existing legislation. Because of this it is unlikely that UK industry would need to spend a significant amount of time familiarising itself with the new legislation.

Under SIC Code 29, some 289,000 people are ‘employed in machinery’. However, the new legislation is relevant only to a proportion of these employees, consisting largely of designers, technical writers and engineers. These employees are estimated to make up around 10 per cent of total employees, and it is estimated that they may need to spend up to five hours familiarising themselves with the new legislation when it is introduced. Using an estimate of the value of this time, implies a one-off cost for familiarisation in the region of £4 million in 2009.

In addition, there may be ongoing costs as a result of relevant staff needing to ‘refresh’ their knowledge of the new legislation and new staff being made aware of the new legislation. However, it is possible that these costs may not be additional costs because they could have been incurred anyway, as there would be a need for similar ‘refreshing’, and education of new staff, for the existing legislation on machinery. In as far as the new legislation requires additional levels of training, over and above that for the existing legislation, this is not expected to be significant, as the new legislation applies to only two new additional types of machinery, and requires ‘partly completed machinery’ in terms of its health and safety requirements to be treated like ‘completed’ machinery. A figure of 10 per cent of the total one-off costs may not be unrealistic, and this would imply annual costs in the region of £0.4 million from 2010 onwards.

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24 Based on SIC Code DK 29. Given the scope and nature of the Machinery Directive it is difficult to give precise estimates, and more businesses could be affected, though to a lesser extent than those in the main sectors affected.

25 Using an estimate of average wages for the relevant employees in 2009 with a 30 per cent mark-up for non-wage labour costs. The SI itself will come into force in the second half of 2008, and is to be operational from 29 December 2009.
(ii) Costs of providing information on machinery and marking of machinery

83. The new Machinery Directive requires manufacturers to provide certain information on machinery in terms of instructions in numerous languages, and in terms of marking machinery with the ‘CE’ mark. However, these requirements are largely contained within the existing Directive and so are not expected to lead to any additional costs to business. Where the scope of the Machinery Directive has been extended to the two new types of machinery this is likely to result in additional costs in terms of instruction provision and marking but these are difficult to quantify at present, because it is unclear how many businesses or products may be affected.

(iii) Costs of providing Technical Files

84. Manufacturers of machinery need to provide technical files on the machinery they produce. However, this is already a requirement of the existing Directive and so is not expected to result in any additional costs to business. Indeed, Annex X of the new Directive may lead to a reduction in the level of existing costs as it provides manufacturers with the option of obtaining approval of their processes as opposed to approval of each type of product they produce. Where the scope of the Machinery Directive has been extended to the two new types of machinery this is likely to result in additional costs, but these are difficult to quantify at present, because it is unclear how many businesses or products may be affected.

(iv) Costs of conformity assessment

85. Manufacturers of machinery need to carry out procedures for assessing the conformity of the machinery they produce, and produce a declaration of this conformity. There is a new requirement to print a generic copy of the Declaration of Conformity with the instructions for use of machinery. This is likely to lead to additional costs to manufacturers but these are not expected to be significant, given that the format of the Declaration is expected to be in the same format as that of the instructions for use. Where the scope of the Machinery Directive has been extended to the two new types of machinery this is likely to result in additional costs, but these are difficult to quantify at present, because it is unclear how many businesses or products may be affected.

86. The new Machinery Directive places specific requirements on manufacturers of partly completed machinery similar to those who produce ‘complete’ machinery. Any additional costs from this are expected to be small, with the main impact being a possible shift of existing costs from users of partly completed machinery to manufacturers of partly completed machinery.

(v) Costs of meeting essential requirements

87. Manufacturers of machinery will need to design and build machinery that satisfies the relevant essential requirements of the new Machinery Directive with respect to the machinery they place on the European market. Where the scope of the Machinery Directive has been extended to the two new types of machinery this is likely to result in additional costs.

88. The new Machinery Directive introduces more specific requirements in terms of the following: ergonomics, lightning protection, provision of seating at workstations, and guard fixings. There is also a requirement to estimate the uncertainty of measurements for noise and vibration reporting. In addition, there are some extra requirements for lifting platforms for people, bringing these more into line with the Lifts Directive.

89. Most of these requirements are not expected to result in significant costs because much modern machinery already meets many of the essential requirements. However, the requirements for guard fixings are expected to result in costs in the region of £1 million per annum based on the estimates of the number of guards used and the average number of fixings per guard.
90. Table 3 outlines current estimates (where they can be made) of the costs to business from BERRs draft SI.

Table 3: An Estimate of costs to UK businesses from BERR’s draft SI (£ million)

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</table>

Costs to Public Sector

91. The existing Machinery Directive which is reflected in current UK legislation requires the Government to undertake a number of tasks to ensure effective implementation of the Directive in the UK. These include direct enforcement of the UK’s Regulations by the Health and Safety Executive (HSE), the Office of Rail Regulation (ORR), and Trading Standards Officers (TSOs) of Local Authorities (LAs), through, for example, reactions to complaints from manufacturers or consumers, or following accidents, and from factory or retail outlet inspections. The current level of this direct enforcement is not expected to be affected significantly by the new Directive.

92. In terms of administering the UK’s Regulations, one-off costs will be incurred in terms of training relevant staff, preparing and issuing new Guidance material, but these are not expected to be significant. Representation of UK interests at European level is not expected to entail any additional significant costs.

Small Firms Impact Test

93. The draft SI is not expected to have a disproportionate impact on small and medium-sized enterprises (SMEs) in the UK, because the new Machinery Directive is not a radical departure from the existing Directive, and little evidence has come to light that the existing Directive has had a disproportionate impact on SMEs.

94. There could be a transfer of some costs from large businesses to SMEs as a result of the requirements on producers of partly completed machinery in the new Directive, and as a consequence of some products that were previously covered by the Low Voltage Directive (LVD) now being covered by the Machinery Directive. However, these costs are not expected to be disproportionate, but rather relate to the level of activity undertaken by a particular business.

95. Moreover, Annex X of the new Directive relating to ‘full quality assurance’ for conformity assessment should be of benefit to SMEs because of, for example, its relatively easier application to the production of prototypes with which SMEs are particularly closely associated.

Competition assessment

96. Since 2002 it has been a requirement that RIAs (now IAs) contain an assessment of the potential impacts on competition of the proposal under consideration. The current competition assessment consists of four questions, to aid assessment of the impact of proposed regulation on markets.

97. The first question asks if the proposed regulation limits the number, or range, of suppliers. This is more likely to be the case if the proposal is to award exclusive rights or create licenses.
The new Machinery Directive, and so BERR’s draft SI, does not limit the ability of businesses to place machinery on the market, but rather requires all businesses doing so to meet similar relevant essential requirements.

98. The second question asks if the proposal indirectly could limit supply by, for example, raising the costs of new compared to existing suppliers, or affecting entry into or exit from the market. The draft SI affects all businesses placing machinery (within its scope) on the market, and costs will be incurred largely depending on the level of activity determined by businesses themselves.

99. The third question asks if the proposal limits the ability of suppliers to compete, for example, by limiting innovation, sales channels, or production processes. The new Machinery Directive is based on the principles of the EU’s ‘New Approach’ which aims to introduce essential requirements but not to specify particular technologies, or production methods.

100. The fourth question asks if the proposal reduces incentives for suppliers to compete by, for example, requiring them to reveal price, cost or sale information, or making it more difficult for consumers to switch supplier. The draft SI does not require businesses to reveal market-sensitive information or restrict consumers in their choice of machinery supplier.

**Enforcement, sanctions and monitoring**

101. The enforcement provisions of member States and the sanctions they apply are not addressed by the new Directive, although Article 19 of the new Directive requires member States to co-operate more effectively between themselves in this regard, and Article 23 requires penalties to be effective, proportionate and dissuasive. Thus, on enforcement, BERR’s draft SI carries forward what is already in place in the UK, with one exception. This exception reflects the fact that since the last SI, the Office of Rail Regulation (ORR) has taken over some of the responsibilities of the HSE, including, at the margins, some that are relevant to the enforcement of the Supply of Machinery Regulations. The ORR is therefore cited in the draft Regulations as an enforcement authority alongside HSE and local weights and measures authorities. On sanctions, the UK authorities believe that the revised set of penalties introduced by an amending SI in 2005 satisfy the criteria of Article 23 and these are therefore carried forward unchanged.

102. There will be some initial training costs to familiarise enforcing authority staff with the new Regulations. However, once this is complete, the annual cost of enforcing the SI will not differ significantly from the current position. At present the products and safety requirements in the proposed SI are covered by the existing Supply of Machinery Regulations 1992, or other more general legislation such as Section 6 of the Health and Safety at Work Act 1974, and so will not introduce new areas of work.

103. Historically, for large-scale industrial machinery the HSE has been the enforcement body. Given its size and nature, such equipment has been monitored by market surveillance, and by inspection on site once it is in use (in tandem with the UK’s Provision of Use of Work Regulations (PUWER)). The ‘New Approach’ basis of the new Machinery Directive is likely to result in more pro-active project work in the HSE, which will be aided by the use of a European database system (ICSMS). These changes will facilitate improvements in information gathering and responses to intelligence which should enable the enforcement authorities to concentrate their resources for enforcement further in line with the principles set out in the Hampton Report (March 2005). Any extra costs of informing the EU Commission of enforcement action concerning the new products brought into scope of the proposed SI will be counter balanced by resulting savings in inspectors’ time due to the SI being more specific to these products and hence easier to apply than the previous more general legislation.
Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

<table>
<thead>
<tr>
<th>Type of testing undertaken</th>
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<th>Results annexed?</th>
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<tr>
<td>Small Firms Impact Test</td>
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</tr>
<tr>
<td>Rural Proofing</td>
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</tr>
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</table>
SPECIFIC IMPACT TESTS

Legal Aid
It is not clear to what extent those who would be subject to the draft SI transposing the Machinery Directive are eligible for legal aid, but as the draft SI is not expected to have any material effect on the criminal or civil liability of those who are subject to the proposed Regulations implementing the Directive, it should not have any impact on legal aid in the UK.

Sustainable Development
The draft SI is not expected to have any significant impact on sustainable development in terms of, for example, greenhouse gas emissions, impacts on air or water quality, or impacts on waste management. The new Machinery Directive, like the existing Directive, provides for levels of protection for users of machinery in relation to exposure to noise.

Carbon Impact Assessment
The draft SI is not expected to have any significant carbon impact. The main aims of the draft SI are to promote the European Single Market, to promote health and safety, and to provide protection for the environment and animals, where machinery is involved.

Other Environment
The draft SI has as one of its main aims protection of the environment and animals where machinery is used. These benefits are discussed in the main text of the Impact Assessment.

Race Equality Assessment
The draft SI does not have as one its aims race equality explicitly. However, one of the aims of the draft SI is to provide equal, and high, levels of health and safety protection for all users of machinery, irrespective of race.

Disability Equality
The draft SI does not have disability equality as one of its aims explicitly. However, in the drafting of the Machinery Directive (2006/42/EC) that the draft SI proposes to implement the impact on disability equality was considered at some length including by the European Parliament during their ‘First Reading’.

There were two main areas of concern. First was that the section on ergonomic requirements should be strengthened to make it clear the extent of the human factors that needed to be considered in the design of machinery. Secondly, that lifting platforms that are mainly used by people with reduced mobility should have the same level of safety requirements as those for the general population, and should not be specifically listed as for disabled persons. In taking this decision it was recognised that persons with impaired mobility needed to have their children and other non-disabled persons accompany them, and there must be no tendency to suggest lower levels of safety requirements for these types of lift. The European Parliament queried if lifts giving access to work stations should have braille controls to make them accessible to persons with visual impairment, but this was not included in the Directive due to the variety of work
stations involved, many of which required a high standard of vision of the worker, an example being lift to the operating position of tower cranes.

**Gender Impact Assessment**

The draft SI to transpose the Machinery Directive impacts on all manufacturers and users of machinery. It is not aimed at overcoming gender inequalities or eliminating barriers to inequality, but the fact that it sets down health and safety requirements for users of machinery should mean that it contributes positively to gender equality.

**Human Rights**

The draft SI is not expected to impact on the rights and freedoms of individuals as set out in the Human Rights Act 1998.

**Rural Proofing**

The draft SI is significant in the rural economy because of the wide range of agricultural applications where products are used that fall within the scope of the new Machinery Directive (though the draft SI, like the new Directive, excludes from its scope agricultural and forestry tractors).

However the draft SI is not expected to have significant impacts on rural areas or circumstances because the treatment of these products has not changed significantly from the old to the new Directive.
### Annex E

**DRAFT SUPPLY OF MACHINERY (SAFETY) REGULATIONS 2008**

**DRAFT TRANSPOSITION NOTE**

<table>
<thead>
<tr>
<th>PROVISION OF DIRECTIVE 2006/42/EC</th>
<th>RELEVANT PROVISION OF REGULATIONS</th>
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<tbody>
<tr>
<td>Article 1(1) (products in scope)</td>
<td>Regulations 4 and 5</td>
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<tr>
<td>Article 1(2) (products out of scope)</td>
<td>Regulations 4(1)(c) and 5(3); Schedule 3</td>
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<td>Article 2(a)</td>
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<td>Whole Article</td>
<td>Regulation 6</td>
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<td>Article 4(1), 4(2) (Member States to ensure machinery and partly completed machinery satisfies essential requirements etc)</td>
<td>All, but see in particular Parts 3 (especially regulation 7(1)) and 6 and definition of “safe” in regulation 2(2).</td>
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<td>Article 4(3), 4(4) (Member States to appoint competent authorities etc)</td>
<td>Schedule 5</td>
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<td>Article 5(1)(a) to (f) (what to do before placing machinery on market)</td>
<td>Regulation 7(2)(a) to (f)</td>
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<td>Article 7(3) (publication of references to harmonised standards)</td>
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<td>Article 7.4 (enabling social partners to have influence at national level)</td>
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<td>Whole Article (disputing harmonised standard before Directive 98/34/EC committee)</td>
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<td>Whole Article (Member State action where “compliant” machinery considered unsafe)</td>
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<td>Article 14(4) (publication)</td>
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- AAC Services
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- API Foils
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- AV Technology Ltd
- Abacus Automation
- Access Technology
- Accord Plc
- Ad Qual Castech Ltd
- Aggreko Generators Ltd
- Agricultural Engineers Association
- Agricultural Engineers Association
- Agricultural Industries Confederation
- Air Products PLC
- Allianz Cornhill Engineering
- Amtri Veritas
- Amtri Veritas
- Angus Council
- Apex Lifts
- Apex Lifts
- Ardent Ltd
- Asta Beab Certification Services
- Astra Zeneca
- Astro Technology Limited
- Automatic Vending Association
- Automation and Lift Limited
- Axel Lifts
- BOC Edwards
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- BVQI Ltd
- Bernard James Consultant
- Black & Decker
- British Aerosol Manufacturers Association
- British Airports Authority
- British Amusement Catering Trades Association
- British Blind and Shutter Association
- British Compressed Air Society
- British Contract Furnishing Association
- British Engineering Manufacturers' Association
- British Industrial Truck Association
- British Industrial Trucks Association
- British Mechanical Power Transmission Association
- British Standards Institute
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- British Standards Institute
- British Standards Institute
- British Textile Technology Group
- Bureau Veritas Inspection Limited
- Bureau Veritas Inspection Limited
- Bureau Veritas Inspection Limited
Liang Zhang  CCQS UK Ltd
Eunice Yang  CEM International Ltd
Ray Lathan  Caterpillar Peterlee Ltd
Janet Asherson  Confederation of British Industry
Jennifer Braithwaite  Clark Eriksson
Richard Hedgecock  Clyde Materials Handling
David Greenman  Concoat Ltd
Nick Williams  Conformance Ltd
Jim Kerr  Consarc Engineering Ltd
Shelley Atkinson-Frost  Construction Confederation
Colin Wood  Construction Plant-Hire Association
Neil Jones  Crane Process Flow Technologies Ltd
Richard Meadows  Cummins Power Generation

David Hind  Davis Derby Ltd
Bryan Fotheringham  Dresser Wayne UK Ltd
Mike Goddard  ETL Ltd
Rupert Hodges  Engineering and Machinery Alliance
Adrian Blades  Electrolux
Ish Buckingham  Elevation
Michael Annett  Enercon Industries
David Evans  Engineers and Managers Association
Steve Walter  Engineering Employers Federation
Clive Tayler  Engineering Equipment & Materials Users Association
Colin Mason  Engineering Industries Association
Ian Fraser  European Commission
Andy Porter  European Hydraulic Tool Manufacturers Assoc

John Walker  Federation of Small Businesses
Ray Williams  GF Lift Hydraulics Limited
Tony Lacey  GHL Liftrucks Ltd.
Nick Ground  GKD Europe Ltd
John McClean  GMB Britain's General Union
Tom Griffiths  Gauge & Tool Manufacturers Association
Leo Darrell  Gilbarco Veeder-Root
Alan Cherry  Global Certification
Martin Gordon  Gordon Design Consultants
Charles Byrne  Graham-Hart Limited
Peter Maufe  Guyson International Ltd

Alan Johnson  HMF (UK) LTD
Rod Cummins  HS Marston Aerospace Ltd
Alan Hulme  HSB Inspection Quality Limited
Ian Clark  Halliburton Manufacturing & Services Ltd
Paul Chinnery  Hayter Limited
Phil Papard  Health & Safety Executive
Steve Shaw  Health & Safety Executive
Ian Simpson  Health & Safety Executive
Peter Lennon  Health & Safety Executive
Chris Hales  Health & Safety Executive
Roger Higgison  Higginson Acoustics Ltd
Mark Jenkins  Huxley Bertram Engineering Ltd

John Rogers  ITW Finishing UK
Ian Roberts  Ian Roberts Consultancy Services
Crispin Dunn-Meynell  International Compressed Air & Allied Machine Committee
Alexander Ehmman  Institute of Directors
Richard Jones  Institution of Occupational Safety & Health
Dominic Cattini  International Association of Drilling Contractors
John Webster International Lifts Company
Andy Austin Intertek Testing & Certification Ltd.
Tim Whiteman International Powered Access Federation Ltd
Gil Male International Powered Access Federation Ltd
Mark Ireland JCB Research
Bob Meadows Jackson Lift Group
Ken Daniels Jones & Shipman International
Keith Lowe Komatsu UK Ltd
Ron Wanless Kone Escalators
Adrian Langmead Kubota (UK) Ltd
John Shallow Kvaener Inc
Paul Laidler Laidler Certification
Greg Lack Land Securities Trillium
JM Leese Landis Lund
Lara Raworth Leisure Link
Bryan Hines Lerch Bates
Malcolm Miles Lift Cert Limited
Robert Lee Lift & Escalator Industry Association
David Fazakerley Lift & Escalator Industry Association
Derrick Bailes Lifting Equipment Engineers Association
David New Lifting Equipment Engineers Association
Paul Eckersley Linde Marketing Ltd
Neil Bennett Linx Printing Technology
Paul Williams Lloyds Register Quality Assurance
Simon Emeny Lloyds Register Quality Assurance
Alison Edwards Local Authorities Coordinators of Regulatory Services
Chris Andrews MIRA Limited
Mike Smith Machinery International
Stephen Fulwell Magnolia House Consultancy
Boris Toinko Makita (UK) Ltd
Frederick Cutler Margins and Safety
Bernie Campbell Mars Drinks
David Linsell McLellan & Partners Ltd
Bryan Whittaker Mechanical and Metal Trades Confederation
Graham Povey Micron Sprayers Limited
Jon Duerr Mitsubushi Electric (uk) Ltd
Mike Chrisp Model Engineer Magazine
Keith Greenwood OIS Plc
Mark Clapham Office of Rail Regulation
Bill Murray Offshore Contractors' Association

Craig Hulatt PP Payne Ltd
Pasc Ruggiero P R Safety Associates
Nick Mellor Pickerings Ltd
Martin Palmer Pilz Automation Technology
David Pochin Pochin PLC
Paul Adorian Powered Access Certification Ltd.
Martin Keay Process & Packaging Machinery Association
Mark Hastings Public Access Ltd
Steve Noakes Pyroban Ltd

Richard Gostling Railway Industry Association
John Lane Ratcliff Tail Lifts Ltd
Alan Barsby Ratcliff Tail Lifts Ltd
Iaun Lindsay Rockwell Automation
Malcolm Thomas Royal & Sun Alliance Insurance PLC
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CONSULTATION ON THE IMPLEMENTATION OF EU DIRECTIVE 2006/42/EC OF THE EUROPEAN PARLIAMENT AND THE COUNCIL OF 17 MAY 2006 ON MACHINERY, AND AMENDING DIRECTIVE 95/16/EC RECAST)

Consultation response form

The closing date for this consultation is 18/12/2007

Responses to this consultation document can be made by to the named person stated in Section 3 - How to respond as shown below:

a) detaching the consultation response form (Annex F) from this document and returning it by post

b) detaching the consultation response form (Annex F) from this document and returning it by fax

c) down-loading the separate consultation response form from our website, saving it as a separate file, and returning it by email.
Consultation Response Form

The closing date for this consultation on the implementation of the new Machinery Directive 2006/42/EC, and amending Directive 95/16/EC, in the United Kingdom is 18/12/2007. You may find it helpful to set out your responses to the Consultation using this Response Form.

Name
Organisation (if applicable)
Address

Return completed forms to:

Peter Baxter-Ludlow or Mike Dodds as per Section 3 on How to Respond

Please tick one box from the following list of options that best describes you.

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<td>Other (Please describe, eg. consultant or private individual)</td>
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Question 1: Do the draft Regulations, as attached, transpose accurately all of the provisions of the directive that require to be transposed into UK legislation? If not please say which provisions you consider have not been properly transposed.

Question 2: Do the draft regulations deal appropriately with any other legal or practical issues raised by the implementation of the Directive in the UK context? If not please explain your response as fully as possible.
Question 3: Do you consider the draft Regulations as framed to be ‘business-friendly’? If not, and the problem is one of drafting, please state which ones are not and suggest a form of words for each that would make them clearer.

Question 4: Do you consider the Regulations as framed make it clear to a manufacturer what he needs to do to bring his products into conformity? If not, please explain why.
Question 5: Article 2 (a) of the Directive defines “machinery” and is transposed by Regulation 4 (2) (a) in a slightly different format. Do you prefer how it has been transposed, or would you prefer to see the text of the directive reproduced here? If neither, what text do you think would provide greater clarity?

COMMENTS

Question 6: Article 2 (g) of the Directive introduces the new concept of “partly completed machinery”. Regulation 5 transposes this in a slightly different format. Is this helpful, and does it work? If not, what wording would make it clearer?

COMMENTS
Question 7: The draft Regulations use the terms “manufacturer” and “authorized representative” as defined in the Directive, but also employ the term “responsible person” in cases where the Directive refers to manufacturers and authorized representatives together. Do you agree with this approach? If not, please provide reasons.

Question 8: Is it clear in the draft Regulations when, and for what purpose, a manufacturer needs to use the services of a Notified Body? If not, please provide reasons.
Question 9: Do you think the partial Impact Assessment (IA) accurately reflects the potential benefits from the draft Regulations transposing the new Machinery Directive in the UK? If not, please explain why, providing, if possible, any evidence or data to support your view.

Question 10: Do you think the partial Impact Assessment (IA) accurately reflects the expected costs from the draft Regulations transposing the new Machinery Directive in the UK? If not, please explain why, providing, if possible, any evidence or data to support your view.
If you have any comments on this Machinery Directive consultation exercise that are not specifically addressed elsewhere in this document please, including the layout of the consultation document itself, please make them known to the department by completing the box below.

**COMMENTS**

We very much appreciate you taking the time to let us have your views. We do not intend to acknowledge receipt of individual responses unless you tick the statement below.

Please acknowledge this reply □

Here at the Department for Business, Enterprise and Regulatory Reform we carry out our research on many different topics and consultations. As your views are valuable to us, are you willing to be contacted again from time to time either for research or to send through consultation documents?

□ Yes □ No

**The Consultation Code of Practise Criteria**

1. Consult widely throughout the process, allowing a minimum of 12 weeks for written consultation at least once during the development of the policy.

2. Be clear about what your proposals are, who may be affected, what questions are being asked and the timescale for responses.
3. Ensure your consultation is clear, concise and widely available.

4. Give feedback regarding the responses received and how the consultation process influenced the policy.

5. Monitor your department’s effectiveness at consultation, including through the use of a designated consultation co-ordinator.

6. Ensure your consultation follows better regulation best practice, including carrying out a Regulatory Impact Assessment if appropriate.

The complete code is available on the Cabinet Office’s web site, address: